

# EXHIBIT B

IN THE COURT OF COMMON PLEAS OF PHILADELPHIA COUNTY  
FIRST JUDICIAL DISTRICT OF PENNSYLVANIA  
CIVIL TRIAL DIVISION

IN RE: PELVIC MESH LITIGATION:

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:  
PATRICIA HAMMONS, : MAY TERM, 2013  
Plaintiff:  
:  
:  
v. :  
:  
:  
ETHICON, INC., et al., :  
Defendants : NO. 3913  
- - -

Monday, December 7, 2015

COURTROOM 246  
CITY HALL  
PHILADELPHIA, PENNSYLVANIA  
- - -

B E F O R E: THE HONORABLE MARK I. BERNSTEIN, J.,  
and a Jury  
- - -

JURY TRIAL VOLUME V

AFTERNOON SESSION

REPORTED BY:  
JUDITH ANN ROMANO, CM, CRR  
CERTIFIED MERIT REPORTER  
CERTIFIED REALTIME REPORTER  
OFFICIAL COURT REPORTER

A P P E A R A N C E S: (Continued)

GOLDMAN, ISMAIL, TOMASELLI, BRENNAN & BAUM, LLP  
BY: TAREK ISMAIL, ESQUIRE  
(admitted pro hac vice)  
564 West Randolph Street, Suite 400  
Chicago, Illinois 60661  
T: 312-681-6000 F: 312-881-5190  
E-mail: tismail@goldmanismail.com  
Counsel for Defendants Ethicon and Johnson and  
Johnson

THOMAS COMBS & SPANN, PLLC  
BY: SUSAN M. ROBINSON, ESQUIRE  
(admitted pro hac vice)  
300 Summers Street, Suite 1380  
Charlestown, WV 25338  
T: 304-414-1800 F: 304-414-1801  
Counsel for Defendants Ethicon and Johnson and  
Johnson

A P P E A R A N C E S:

KLINE & SPECTER, A Professional Corporation  
BY: SHANIN SPECTER, ESQUIRE  
BY: KILA B. BALDWIN, J.D., ESQUIRE  
1525 Locust Street  
The Nineteenth Floor  
Philadelphia, Pennsylvania 19102  
T: 215-772-1000 F: 215-735-0937  
E-mail: shanin.specter@klinespecter.com  
kila.baldwin@klinespecter.com  
Counsel for Plaintiff Hammons

MAZIE, SLATER, KATZ & FREEMAN  
BY: ADAM M. SLATER, ESQUIRE  
103 Eisenhower Parkway  
Roseland, New Jersey 07068  
T: 973-228-0454 F: 973-228-0303  
E-mail: aslater@mskf.net  
Counsel for Plaintiff Hammons

DRINKER BIDDLE & REATH, LLP  
BY: MOLLY E. FLYNN, ESQUIRE  
One Logan Square, Suite 2000  
Philadelphia, Pennsylvania 19103-6996  
T: 215-988-2836 F: 215-988-2757  
E-mail: molly.flynn@dbr.com  
Counsel for Defendants Ethicon and Johnson and  
Johnson

TUCKER ELLIS, LLP  
BY: MATTHEW P. MORIARTY, ESQUIRE  
950 Main Avenue, Suite 1100  
Cleveland, Ohio 44113-7213  
T: 216-696-2276 F: 216-592-5009  
E-mail: matthew.moriarty@tuckerellis.com  
Counsel for Defendants Ethicon and Johnson and  
Johnson

(Hammons v Ethicon, et al.)

- I N D E X -

WITNESSES	VD	DR	CR	RD	RC
SCOTT CIARROCCA					
By Mr. Ismail .....					160
By Mr. Slater .....					180
ANNE M. WEBER, MD					
By Mr. Slater .....	213		235		

E X H I B I T S

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1 **(Ciarrocca - Recross)** Page 197

2 Q To give increased patient comfort, right?

3 **A That's what this is stating.**

4 Q You talked a little bit with counsel about

5 some clinical evidence about what would happen when

6 mesh had to be removed? Remember you mentioned

7 that?

8 **A I think we had a couple of discussions about**

9 **that.**

10 Q Do you have the Clinical Expert Report handy,

11 that report document that we have been talking about

12 for a couple of days?

13 **A I have a version of it. I don't know that I**

14 **have the final signed version here.**

15 Q You do. It's Exhibit P2137. Do you remember

16 counsel asked you to look at it?

17 **A I am holding P680. I don't know if it's the**

18 **same thing.**

19 MR. SLATER: Your Honor, to save time

20 should I approach?

21 THE COURT: You can pass up whatever

22 you like.

23 MR. SLATER: I don't have another copy.

24 THE WITNESS: I am sorry 2137? It

25 found its way up.

1 **(Ciarrocca - Recross)** Page 198

2 Q So you had clinical evidence about the very

3 critical question of what would happen when mesh had

4 to be removed from a woman's body due to

5 complications. That's what you told counsel, right?

6 **A I don't know that we had specific clinical**

7 **evidence. I said that I think the only way you**

8 **would be able to evaluate that is through an**

9 **evaluation of complications from that clinical data.**

10 **That's really the only thing I can imagine.**

11 Q So we are back to the starting point we were

12 at Friday, which is it's a question you did not look

13 at to your knowledge, is that right?

14 **A I am sure Medical Affairs would have looked at**

15 **all the complications.**

16 Q You have no knowledge that they did, you have

17 no evidence of it as you sit here now, right?

18 MS. ISMAIL: Objection, Your Honor.

19 THE COURT: Objection sustained.

20 That's two questions.

21 Q You have no evidence as you sit here now that

22 Medical Affairs actually evaluated that question,

23 right?

24 **A I didn't sit in a room and watch them look at**

25 **that specifically, no.**

1 **(Ciarrocca - Recross)** Page 199

2 Q And in this Clinical Expert Report, that key

3 paragraph "Clinical Evidence," where you said you

4 were looking for more than a blank space? Do you

5 remember that?

6 **A Yes, I do.**

7 Q Does it talk about removal of mesh and what

8 can happen when you remove mesh?

9 MS. ISMAIL: Objection, Your Honor,

10 repetitious.

11 THE COURT: Overruled.

12 **A I don't think it speaks there specifically.**

13 **One of those articles referenced it we may have**

14 **talked about.**

15 THE COURT: Wait a minute, the question

16 doesn't talk about it. Does it talk about it?

17 THE WITNESS: No, she is just

18 referencing different studies.

19 THE COURT: So it doesn't talk about

20 it, right?

21 THE WITNESS: Yes, correct.

22 THE COURT: Anything further?

23 MR. SLATER: Just checking my notes,

24 Your Honor, I am almost done, I think.

25 (Pause.)

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2 MR. SLATER: No other questions, Your

3 Honor.

4 THE COURT: Is anything further?

5 MS. ISMAIL: There is not, Your Honor,

6 thank you.

7 THE COURT: You may step down.

8 - - -

9 (The witness is excused.)

10 - - -

11 THE COURT: Next witness.

12 MR. SLATER: Your Honor, if we can have

13 Five minutes just to make the transition, it

14 would be helpful.

15 THE COURT: We will take ten minutes.

16 (A brief recess is taken.)

17 - - -

18 (The following transpired in open

19 court.)

20 THE COURT: We are on Witness Weber.

21 MR. SLATER: Yes, Your Honor.

22 THE COURT: Is that Dr. Weber?

23 MR. SLATER: Yes, Your Honor.

24 THE COURT: And Dr. Weber prepared a

25 several-hundred page report, is that correct?

**(Hammons v Ethicon, et al.)**

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MR. SLATER: Multiple reports, her initial report was 520 pages.

THE COURT: I will take an offer of proof.

MR. SLATER: The testimony we will provide will not, for the most part, overlap. It will be her qualifications, her materials reviewed, she will touch base on alternative options being viable and safe --

THE COURT: Counsel, what will her testimony be?

MR. SLATER: That is what I am saying.

THE COURT: No, you told me she will touch base on something. I don't want topics, I want an offer of proof.

MR. SLATER: I am just concerned, Your Honor, about laying out my whole direct for the defense right now.

THE COURT: If you don't want to give me an offer of proof you don't have to, but it may make their motion to preclude pretty easy.

MR. SLATER: She is going to offer the opinion that there were safer alternatives available at the time, and she is an expert

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MR. SLATER: I would have to pull the exhibits out. There is charts on findings of recurrence rate --

THE COURT: Can it be summarized?

MR. SLATER: In part, for example, a 20.7 percent exposure rate at one year in the French study, and she will also be pointing out that the recurrences in the U.S. study were undercounted, so that study also failed the endpoint.

THE COURT: Anything else?

MR. SLATER: Yes. Those are examples, that's not complete, but her opinions on the review of the data has to do with recurrences and exposures/erosions, and the overall benefit-risk profile shown by these studies.

In the context of the Gynemesh PS study, she will be shown pages from the professional education deck that was in use when Dr. Baker was trained and there will be information in that about the Gynemesh PS study which she will point out is incorrect. And there is one other page in there about the recurrence rates with other procedures and she

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with regard to most of them -- with regard to all of them.

THE COURT: Anything else?

MR. SLATER: She is going to speak briefly about Ultrapro in the Prolift+M and testify that would have been a safer alternative.

As a matter of foundation, I will be going through an Ethicon report on mesh erosions and laying a foundation and asking her opinions on the significance of various passages in an Ethicon document she has relied on. I will be doing that with regard to two documents. I will then be taking her through the actual studies that we have been hearing about in this trial, the Gynemesh PS study, the TVM studies, and she will be going through -- she actually reviewed all of the case report forms in those studies, the actual patient level data, the protocols, the reports, and did her own independent analysis, and she will be showing the jury the data that she found based on her independent analysis.

THE COURT: Which will be what?

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will simply opine those are incorrect rates.

She is familiar with all the literature that is cited.

She will then go through a database of data from Vince Lucente, the surgeon we heard about during the trial. Through subpoenas we were able to get his, what's called an Investigator Initiated Study database. Dr. Lucente got funding from Ethicon to evaluate his own patients, and it was over 500 patients. Dr. Weber actually went through all of the data and evaluated it and came up with what his erosion rates, recurrence rates, and reoperation rates were and will compare those to what was represented in a public abstract and other publications by him, to point out that the complications when we finally got his own internal data were far worse and far higher than anything he had ever published before.

And that's all data that's been relied upon by Ethicon, and in fact, he was one of the study investigators in both the Gynemesh PS and TVM studies, and we learned that he had

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2 some inconsistencies in how he recorded data,  
3 and that will be probably referenced.

4 Time permitting, depending on how fast  
5 we move, we have two PowerPoints from those  
6 design control processes, where Dr. Weber has  
7 just listed medically, medical harms that were  
8 not evaluated in that design control process.

9 She will offer an opinion on the  
10 Clinical Expert Report that it did not validly  
11 evaluate the safety and efficacy. I will not  
12 walk through it at all, I will simply ask if  
13 she is familiar with it and her opinion. She  
14 has a foundation of knowing all of this, I  
15 will not go through any of what we already  
16 heard.

17 She will talk about a particular study  
18 by Dr. Lowman, the defense expert on  
19 dyspareunia which they are relying on and had  
20 in their opening PowerPoint, and she will  
21 point out that the data reported is misleading  
22 and explain why. That's my word "misleading".  
23 She will show the true dyspareunia rates based  
24 on the data that's available in those studies.  
25 Counsel had a 16 percent rate on the board, we

1 (Hammons v Ethicon, et al.) Page 206

2 will show it as high as 39 percent based on  
3 the data available.

4 She will then be shown the abstract of  
5 a presentation by the TVM group in 2005, where  
6 they characterized the 6.7 percent erosion  
7 rate as high. A subsequent article on the  
8 same group of 687 patients, where they had an  
9 11.3 percent erosion rate in 3.6 months and a  
10 33.6 percent complication rate at that time  
11 and characterized this as a relatively high  
12 incidence of post-surgical complications. She  
13 will obviously have opinions as she goes  
14 through this, but we are going to walk through  
15 literature.

16 Then we are going to go through a  
17 poster presentation by the Ethicon TVM group,  
18 where they said they needed to study the  
19 procedure further before they would recommend  
20 that it be used in young women or for primary  
21 prolapse repair, and she will be in agreement  
22 with that, that they needed much more study.

23 She will look through a PowerPoint on  
24 the TVM group presentation, where they said it  
25 actually should be placed in women with stage

1 (Hammons v Ethicon, et al.) Page 207

2 three or four symptomatic prolapse where it's  
3 actually causing symptoms. She will then be  
4 asked about another article by the TVM group  
5 where they did ultrasound evaluations of the  
6 Prolift and show that 89 percent of the women  
7 had moderate to severe mesh retraction shown  
8 on ultrasound with significant increase in the  
9 thickness of the mesh, and then go to a  
10 presentation by the same doctors where with  
11 those patients they showed that 19.6 percent  
12 of those women had painful vaginal  
13 examinations due to mesh contraction.

14 She will authenticate an article by an  
15 author named Diwadkar, and point out that the  
16 dyspareunia rate in a meta-analysis was shown  
17 for suture repairs to be only 1.5 percent with  
18 a reoperation rate lower than with mesh.

19 And finally, she will talk about the  
20 ACOG, American College of Obstetricians and  
21 Gynecologists, February 2007 practice  
22 bulletin, which she authored, so I will intend  
23 to display it to the jury, and the primary  
24 thing I am going to show the jury is that she  
25 opined in that that this procedure should be

1 (Hammons v Ethicon, et al.) Page 208

2 deemed experimental, these tissue mesh kit  
3 procedures should be experimental. And then I  
4 am going to bring out that that was changed  
5 later that year by ACOG and they took the word  
6 "experimental" out, and then what I intend to  
7 do is display the letter she wrote to the  
8 editor of the *International Urogynecology*  
9 *Journal* on August 8, 2009, where she took  
10 issue with the change and expressed her views  
11 on why that was wrong and why this should  
12 remain experimental. And I intend to have  
13 her -- it's a one-page letter -- to literally  
14 read it to the jury because that is the full  
15 synopsis of the opinions she formed and they  
16 were all formed before she ever spoke to  
17 counsel.

18 And that will be, I believe, other than  
19 asking her a few questions about the  
20 risk-benefit profile not being acceptable  
21 based on the literature and the studies she's  
22 talked about, that will be the end of her  
23 testimony.

24 THE COURT: So what if anything is she  
25 unqualified for?

1 (Hammons v Ethicon, et al.) Page 209  
2 MS. ROBINSON: Your Honor, Dr. Weber  
3 hasn't practiced medicine since the year of  
4 2005. She hasn't been licensed since 2007.  
5 The last time she performed a surgery was  
6 in --  
7 THE COURT: Speak a little louder.  
8 MS. ROBINSON: The last time she  
9 performed surgery was 2004, prior to Prolift  
10 even coming on market. She has never  
11 implanted a Prolift, she has never seen a  
12 patient who had a Prolift, she never addressed  
13 complications with anybody involving Prolift.  
14 She is simply unqualified to opine on Prolift  
15 and its risk/safety profile, and she is  
16 unqualified to opine on causation factors  
17 related to this particular plaintiff.  
18 THE COURT: I didn't hear anything  
19 about that. Is she going to testify about  
20 this particular plaintiff and causation  
21 factors?  
22 MR. SLATER: I do not intend to elicit  
23 any opinions specific to the plaintiff.  
24 THE COURT: She is not going to testify  
25 to that. Any other reasons why she is

1 (Hammons v Ethicon, et al.) Page 210  
2 unqualified?  
3 MS. ROBINSON: She is unqualified to  
4 testify about the education that doctors  
5 undergo to implant Prolift and the proper way  
6 to do that and the proper way to teach that.  
7 THE COURT: Did you say that?  
8 MR. SLATER: The only thing I said is I  
9 am going to --  
10 THE COURT: Did you say that?  
11 MR. SLATER: I did not say that. I am  
12 not going to ask that question.  
13 THE COURT: I don't understand, was  
14 that a waste of time or --  
15 MS. ROBINSON: He was talking about Dr.  
16 Baker's education, the professional education  
17 that was provided to Dr. Baker. I understood  
18 that she was --  
19 THE COURT: She is not qualified to  
20 testify about the professional education  
21 provided to Dr. Baker? Is that it? What is  
22 ACOG?  
23 MS. ROBINSON: The first part about  
24 ACOG --  
25 THE COURT: What is it?

1 (Hammons v Ethicon, et al.) Page 211  
2 MS. ROBINSON: ACOG is the American  
3 College of Obstetrics and Gynecology.  
4 THE COURT: Did she write something on  
5 their behalf on this topic?  
6 MS. ROBINSON: She wrote a bulletin  
7 regarding prolapse.  
8 THE COURT: Did they publish that  
9 bulletin?  
10 MS. ROBINSON: It was published, yes.  
11 THE COURT: Was she qualified at that  
12 time? Did ACOG consider her qualified to  
13 publish that bulletin across the country for  
14 doctors to read?  
15 MS. ROBINSON: With regard to the  
16 condition of prolapse, yes, Your Honor. But  
17 the second point I want to add about ACOG is  
18 that we have already heard from Dan Elliott,  
19 Dr. Elliott, who has testified about ACOG,  
20 testified exactly as to what counsel had just  
21 indicated, which was there was a word  
22 "experimental" put in the ACOG bulletin, it  
23 was removed, and he testified about that  
24 process. So that's already been covered.  
25 He testified at length about mesh

1 (Hammons v Ethicon, et al.) Page 212  
2 contracture and I believe the particular study  
3 that she is going to talk about. He testified  
4 at length about contracture, the risk-benefit  
5 safety profile. He testified about the TVM  
6 study and that it failed its primary endpoint.  
7 He testified about safer alternatives, and he  
8 testified about physician education.  
9 THE COURT: Your objection is  
10 overruled. Are we ready to bring the jury in?  
11 MR. SLATER: Your Honor, I am going to  
12 need a couple of minutes to set up.  
13 THE COURT: I am sorry, did you leave  
14 something out?  
15 MS. ROBINSON: Yes. There was one  
16 specific objection concerning the Lucente  
17 database that counsel mentioned. The witness  
18 has gone through a database that was acquired  
19 by subpoena through a third party, that being  
20 Mr. Lucente and his practice group. There is  
21 no evidence that that database is a final  
22 database, that it had been vetted, that all of  
23 the patients had been seen and their  
24 information reported in that database. In  
25 fact, the testimony --

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2 THE COURT: You mean the database

3 itself would be impermissible?

4 MS. ROBINSON: Yes.

5 THE COURT: An expert is entitled to

6 rely on things otherwise impermissible in

7 evidence. So that objection is overruled as

8 well.

9 (A brief recess is taken.)

10 (The jury enters the courtroom at 3:37

11 p.m.)

12 THE COURT: Counsel, your next witness.

13 MR. SLATER: Thank you very much, Your

14 Honor. The Plaintiff calls Dr. Anne Weber.

15 - - -

16 (ANNE MARGARET WEBER, M.D., is duly

17 sworn.)

18 THE COURT: Please be seated. I

19 understand you have some medical condition if

20 you would prefer to stand.

21 THE WITNESS: I would prefer to stand.

22 - - -

23 DIRECT EXAMINATION (Qualifications)

24 - - -

25 BY MR. SLATER:

(Weber - Direct - VD) Page 214

1

2 Q Good afternoon, Dr. Weber.

3 A Good afternoon.

4 Q I would ask you as best you can to keep your

5 voice up and project so the jury hears what you have

6 to say, okay?

7 A Yes.

8 Q Please tell the jury just for the record what

9 your name is and where you live?

10 A My name is Anne Margaret Weber, and I live in

11 Baltimore, Maryland.

12 Q We have put in front of you something that we

13 have marked as Exhibit 3384. What is that?

14 A This is my CV.

15 Q What does that mean? What's in there?

16 A So in professional life you make a record of

17 your experiences, education in the medical field, if

18 you are in academics, the articles you have written,

19 presentations you have given, honors received, and

20 so on.

21 Q If you need to refer to it you are certainly

22 welcome to, I am going to ask you some questions

23 about that now, okay?

24 A Yes.

25 Q Please tell the jury about your educational

(Weber - Direct - VD) Page 215

1

2 background, where did you go to college, take us

3 through medical school?

4 A I graduated from college at the University of

5 Maryland in College Park, and then I went to medical

6 school also at University of Maryland, which is in

7 Baltimore.

8 Q And what years are we talking about?

9 A I graduated from college in 1983 and then

10 medical school in 1988.

11 Q And after you went to medical school, take the

12 jury through where you went and what you did and

13 what years, please?

14 A After graduating from medical school, I went

15 to an obstetrics and gynecology residency in

16 Hartford, Connecticut that was four years long, and

17 after that I completed a one-year fellowship in

18 advanced pelvic surgery at the Cleveland Clinic in

19 Ohio.

20 Q What is a residency, just very briefly?

21 A So a residency is training in the specific

22 field that you have chosen. So that involves care,

23 in my field obstetrics and gynecology, in all the

24 phases of caring for women throughout their lives,

25 during pregnancy and childbirth and afterwards, and

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1

2 then as they age, and what turned out to be my

3 specialty, caring for women with pelvic floor

4 disorders.

5 Q You did a fellowship you said at the Cleveland

6 Clinic in advanced pelvic surgery. First, what is

7 the Cleveland Clinic?

8 A The Cleveland Clinic is what's called a

9 tertiary referral clinic. We also provided primary

10 care to people in the community of Cleveland, but we

11 also served as a resource to people who had more

12 complicated problems, where they may have exhausted

13 the resources in their local community and have a

14 problem that needed to be addressed by people who

15 specialized in that kind of care.

16 Q How large is the Cleveland Clinic?

17 A Large. At the time I was there, it had over

18 10,000 employees with an adjoining hospital that had

19 400 beds.

20 Q You said your fellowship was in advanced

21 pelvic surgery. What specifically does that mean?

22 A After I graduated from residency, I decided

23 that to really become as proficient as I felt I

24 needed to be in performing surgery, I wanted an

25 extra level of training. So the fellowship in



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advanced pelvic surgery provided four months of training in oncologic surgery, which is the kind of surgery that women have to go through if they have cancer, reproductive endocrinology, which is for women who have hormonal or infertility problems, and that focused on laparoscopic surgery, and then the remaining four months is spent in the section of the department that cared for women with pelvic floor disorders. So surgical treatments or prolapse and urinary incontinence.

Q And when you finished your fellowship in 1993 did you join the staff in the Department of Obstetrics and Gynecology at Cleveland Clinic?

A Yes.

Q What did that mean, now that you are on the staff at the Cleveland Clinic in the OB-GYN department, what did your practice become?

A So I was focused solely on gynecology. I actually had never practiced obstetrics despite going through all of that training.

In my practice of gynecology, at the beginning I was seeing women for all kinds of problems, abnormal bleeding, fibroids, menopause, and also to a certain degree, pelvic floor

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disorders, but at that early point in my career that wasn't a focal point. So I had an office practice where I was seeing women in an office setting, and then also surgery.

Q Tell us how your practice evolved going forward from 1993 onward?

A So in the same way I had chosen to do a fellowship in advanced pelvic surgery, after a few years in practice I decided that I wanted to focus exclusively on women with pelvic floor disorders. So with the support of my chairman, we changed my office practice so that I would concentrate on seeing women with those kind of problems, and well-woman care or other kinds of problems would be seen by the other gynecologists in the department.

Q And when you talk about pelvic floor disorders, very generally, what does that mean?

A So as I mentioned earlier, prolapse, which I know you have heard quite a bit about already, urinary incontinence, bowel problems. I also interacted extensively with my colleagues in urology if this was a more complicated problem than just straightforward urinary incontinence, for example, and my colleagues in the colorectal department for

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women who had problems in the bowel area.

Q Doctor, in your time at the Cleveland Clinic did you have teaching responsibilities in the fellowship program?

A Yes.

Q What does that mean?

A So at the time I completed the fellowship which was only one year, we continued on that for several more years. So the fellows would come, just as I had, to advance their surgical training, and I was involved with them in the office, they would come with me as I saw patients, and then they would also be with me in surgery, where with my close supervision they were being taught, or I taught them how to perform these kinds of surgeries.

They also had a research component to their fellowship, so I also contracted with them in developing their ideas, designing a research project and carrying it out.

Q Were you Board certified?

A Yes.

Q By what board?

A The American Board of Obstetrics and Gynecology.

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Q And we have heard about what that means so I am not going to take you through it.

You were the Director of Clinical Research in the Department of Obstetrics and Gynecology, what does that mean?

A Yes. So my chairman developed that role for me after I completed a graduate program at the University of Michigan. Another decision I made in my career was that I wanted to focus on research, and I felt that to really be able to design and perform the research at the highest quality, I needed more training than I had in my residency and even in my fellowship. So I decided to attend a program at the University of Michigan that was three years long, and after that I received a masters degree in clinical research design and statistical analysis.

So with that extra training and experience, my chairman created this role as Director of Clinical Research in the department so that I could bring my expertise to assist the other faculty members, fellows, residents, medical students, so that I could also enrich their research activities as well.



1 (Weber - Direct - VD) Page 221

2 Q What does clinical research design and

3 statistical analysis encompass? What does that mean

4 that you got a masters degree in that field?

5 A So that really provided me with a very strong

6 foundation in all of the different kinds of study

7 designs, from observational studies, where you just

8 observe people over time and see what happens to

9 them, and all the way up to randomized trials, that

10 I know you probably heard a bit about, but the only

11 kind of trial where you can actually draw a

12 conclusion about cause and effect, where -- none of

13 the other study designs allow you to do that, there

14 are just too many variables around that you don't

15 have a way of controlling. But in a randomized

16 trial the two groups are developed in a way that

17 they should be comparable. And so when you get to

18 the end of the study, if everybody was equal at the

19 start, then differences in the two groups at the

20 end, you should be able to say, okay, this group got

21 Treatment A and this is how they turned out and this

22 group got Treatment B and this is how they turned

23 out. So we can say, okay, Treatment A did this

24 compared to Treatment B. And that's the only study

25 design where you can do that.

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2 So I received training in designing

3 those studies, statistical analysis as well, so that

4 I could understand what were the appropriate tests

5 to perform when -- first of all, in setting up the

6 study, to set up correctly, and in the end in

7 analyzing the data to be sure that the data were

8 being represented accurately and in a way that

9 people could read and understand how this meant and

10 how significant it would be.

11 Q Okay. In 1999 you became involved with the

12 National Institutes of Health, correct?

13 A Yes.

14 Q Please tell the jury, what is the National

15 Institutes of Health, and then we will talk about

16 your involvement.

17 A So the National Institutes of Health is a

18 branch of the government that funds research around

19 the country, and actually around the world. They

20 also have their own research establishment in

21 Bethesda, Maryland, and they grant money to

22 investigators at universities to perform their own

23 research projects.

24 Q And how did you become involved with the

25 National Institutes of Health, what happened?

1 (Weber - Direct - VD) Page 223

2 A So the leaders in the field of urogynecology,

3 which is what we call the specialty that takes care

4 of women with pelvic floor disorders, realized that

5 the research that had previously been done in the

6 field wasn't as strong as it could be and wasn't the

7 kind of research that was really helping us decide

8 what is the best way to take care of women with

9 these problems. So they had a meeting with the

10 leaders at NIH and discussed what could be done, and

11 the NIH decided to create a new program that would

12 provide a boost of research funds to investigators

13 to start researching the problems of female pelvic

14 floor disorders.

15 And so I applied for that job, and with

16 my additional training and education in research,

17 that's not something that a lot of gynecologists

18 have, and so I was hired for that job.

19 Q And what was your title?

20 A I was the Project Officer for the Female

21 Pelvic Floor Disorders unit.

22 Q And were you the first one to hold that

23 position?

24 A Yes.

25 Q And what did you have to do in that role, in

1 (Weber - Direct - VD) Page 224

2 general terms, I don't want to go all day on it.

3 It's important to just give the jury a sense of what

4 you had to do in that position as the first program

5 director?

6 A As I mentioned, the general idea was to infuse

7 a boost of research funds into the academic

8 community. So we had several initiatives where

9 researchers were invited to submit applications and

10 we set aside money that would be devoted to the best

11 applications in that group. And I also developed a

12 network of institutions -- this was also

13 competitive. They submitted applications and an

14 independent group scored the applications to see

15 which were best, and then a group of seven

16 institutions and another institution that managed

17 the data were selected to design and perform trials

18 across the country.

19 It just makes it so much easier when

20 you have a group of people working on the same

21 problem than just single investigators at their own

22 institution who will have as many patients as they

23 have, but you can see if you expanded that by seven

24 times and you had all these bright brains together

25 designing these studies and getting patients

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1 enrolled in these studies, it was possible to do

2 research at a very high caliber and accomplish it

3 more quickly.

4 Q In your CV I saw a reference to called

5 something called the standardization of terminology

6 for pelvic floor disorders. What does that mean and

7 what was your involvement with that?

8 A So as I mentioned, there had come a

9 realization that the research in urogynecology was

10 not as robust as it could be and should be, and part

11 of the problem was that doctors were just using

12 different words to describe the same things, but

13 when you write that down in a paper it becomes very

14 hard to be able to say, Well, Dr. X said this and

15 Dr. Y said that, are they saying the same things or

16 different things.

17 So I decided that it would be fruitful

18 to hold a meeting, a two-day meeting with scientists

19 around the world and sit everybody down to come up

20 with a set of terms that everybody could use so

21 everyone is speaking the same language, basically.

22 And then I authored a report, which is what

23 Mr. Slater is referring to, to publish that in the

24 literature so that everybody could see that and

25

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1 begin to use the same language.

2 Q I have seen in your CV that you have published

3 articles in the peer-reviewed literature. You have

4 just alluded to that?

5 A Yes.

6 Q I see about a hundred or so in here?

7 A Yes.

8 Q Just very briefly, what does it mean for you

9 to publish an article in peer-reviewed literature?

10 A So the literature that Mr. Slater is referring

11 to is published in professional journals. Every

12 medical scientific branch has their own set of

13 journals that researchers publish in, and the

14 meaning of peer reviewed is that once an author or a

15 scientist submits an article to that journal, it's

16 then reviewed by peers, which are other scientists

17 who then judge the article, decide if the science is

18 robust, if the results have been recorded well, and

19 decide if that would make a contribution to the

20 literature overall.

21 Q Have you yourself acted as a peer reviewer?

22 A Yes.

23 Q Can you estimate the number of journals you

24 acted as a peer reviewer over the years?

25

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1 A In my busiest time in my academic career I

2 would say 15.

3 Q As a peer reviewer what were you doing?

4 A I would receive the manuscript that other

5 authors had submitted to this journal in particular,

6 I would receive that and then be asked to review the

7 manuscript and judge its quality, whether the

8 methods were strong enough to actually answer the

9 question that had been posed, whether the results

10 had been analyzed and recorded, and how reliable was

11 that conclusion going to be. And then I would make

12 my comments, which are sent back to the editor, with

13 other reviewers, and then feedback goes to the

14 authors.

15 Q Are you currently acting as a peer reviewer?

16 A Yes.

17 Q For what journal?

18 A The *British Journal of Obstetrics and*

19 *Gynecology*, the *American Journal of Obstetrics and*

20 *Gynecology* and the *International Urogynecology*

21 *Journal*.

22 Q What I would like to do as part of going

23 through your background, what I have handed you

24 is --

25

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1 THE COURT: Counsel, didn't you say she

2 had written 200 or so peer-reviewed articles?

3 MR. SLATER: I think it was about a

4 hundred peer-reviewed articles.

5 THE COURT: Do you intend to ask her

6 about every one on qualifications?

7 MR. SLATER: I absolutely do not.

8 THE COURT: Are you going to ask her

9 about any?

10 MR. SLATER: This one.

11 THE COURT: Why?

12 MR. SLATER: I think it's an important

13 article in the medical literature in this

14 field.

15 THE COURT: Then she can talk about it

16 if she is qualified to provide testimony.

17 Proceed.

18 BY MR. SLATER:

19 Q Putting the article down, in the course of the

20 studies that you performed and the articles that you

21 have written, did you perform a randomized control

22 trial comparing suture-type procedures with mesh

23 procedures?

24 A Yes.

25

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1

2 Q Had there ever been a randomized control trial

3 addressing that question?

4 **A No.**

5 Q And that was published when?

6 **A 2001.**

7 Q In 2001, I believe you left the Cleveland

8 Clinic to go to Magee-Womens Hospital at the

9 University of Pittsburgh?

10 **A Yes.**

11 Q Why did you do that?

12 **A I --**

13 THE COURT: What do you do now?

14 THE WITNESS: I serve as a consultant

15 for Mr. Slater.

16 THE COURT: Do you do anything else

17 besides that now?

18 THE WITNESS: Yes.

19 THE COURT: What else?

20 THE WITNESS: As we mentioned, I serve

21 as a peer reviewer for medical journals. I

22 serve as a mentor for medical students at my

23 alma mater, the University of Maryland. And I

24 also write. I just completed a commentary,

25 for example, for the *British Journal of*

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1

2 *Obstetrics and Gynecology* in relation to an

3 article that I had reviewed.

4 THE COURT: Okay, what did you do

5 before you did these things? Did you have a

6 different position?

7 THE WITNESS: Yes.

8 THE COURT: What was that?

9 THE WITNESS: The timeframe, if I can

10 ask, Your Honor?

11 THE COURT: How long have you been a

12 consultant for Mr. Slater?

13 THE WITNESS: Since 2010.

14 THE COURT: And how long have you been

15 writing peer-reviewed journal articles?

16 THE WITNESS: Since 1988.

17 THE COURT: And how long have you been

18 reviewing, a peer reviewer for journal

19 articles?

20 THE WITNESS: Since 1992.

21 THE COURT: What did you do before you

22 started working for Mr. Slater?

23 THE WITNESS: After I retired from my

24 surgical practice in 2004, and my clinical

25 practice in 2006 -- we can talk about why that

(Weber - Direct - VD) Page 231

1

2 had to happen -- I continued working for the

3 NIH until the end of 2007, and then primarily

4 for health reasons, I stepped down from that

5 position, when I was also confident that it

6 would be able to carry on under new

7 leadership, and it has. And then I continued

8 medical editing and writing until I became a

9 consultant with Mr. Slater.

10 THE COURT: This says 1999 to 2007,

11 Medical Officer, Program Director for Research

12 on Female Pelvic Floor Disorders. What would

13 that be?

14 THE WITNESS: Yes, so that's my work

15 with the NIH that I was describing. From

16 1999, after I completed my masters degree, to

17 2007, when I retired from that position.

18 THE COURT: Okay, and you retired in

19 2007; is that right?

20 THE WITNESS: From the NIH, yes.

21 THE COURT: Any further questions on

22 qualifications?

23 MR. SLATER: Just a few, Your Honor.

24 BY MR. SLATER:

25 Q In 2001 you went to Magee-Womens Hospital at

(Weber - Direct - VD) Page 232

1

2 the University of Pittsburgh, why did you do that?

3 **A The primary reason for doing that was to start**

4 **a new fellowship program there, which they hadn't**

5 **had in the past, and I did develop the program there**

6 **and served as program director until I left the**

7 **University of Pittsburgh.**

8 **At this point the fellowship in what**

9 **was now called female pelvic medicine and**

10 **reconstructive surgery, which is just a long name**

11 **for urogynecology had become a three-year**

12 **fellowship. Remember I went through a one-year**

13 **fellowship when no other types were available, but**

14 **by that point 3-year fellowships were available.**

15 Q Did you continue to teach at University of

16 Pittsburgh Medical School?

17 **A Yes.**

18 Q Were you a licensed physician and in what

19 states?

20 **A Yes. I was licensed in Connecticut, Ohio, and**

21 **Pennsylvania.**

22 Q And you stopped practicing medicine about

23 2006. Just tell the jury briefly why that was?

24 **A Yes. So unfortunately, I sustained an injury**

25 **in 1996 and worked through that for quite awhile,**

1 (Weber - Direct - VD) Page 233

2 but eventually I found that the demands were too

3 much for me and so, as I mentioned, I retired from

4 my surgical practice first and then continued with

5 my clinical practice. I have a pain syndrome and I

6 am standing here because it's more comfortable for

7 me to stand than it is to sit for prolonged periods.

8 Q Did you maintain your medical license after it

9 lapsed or did you let it go?

10 A No.

11 THE COURT: After it lapsed she let it

12 go. Any further questions?

13 BY MR. SLATER:

14 Q In looking at your CV, there were a few things

15 in the Professional Service section, I just want to

16 ask you what this means: That you were a member of

17 the Board of Directors of the American Urogynecology

18 Society 1988 to 2001 and 2003 to 2006. What does

19 that involve?

20 A The American Urogynecology Society is a

21 professional organization where doctors and

22 scientists with similar interests meet. The Board

23 of Directors, of which I was a member, serves to

24 provide direction to the organization in terms of

25 what they would like to focus on in the future.

1 (Weber - Direct - VD) Page 234

2 Q Were you in examiner for the American Board of

3 Obstetrics and Gynecology?

4 A Yes.

5 Q What does that mean?

6 A In order for doctors to become Board certified

7 they have to go through an oral examination. So I

8 was one of the doctors who served as an examiner,

9 testing the younger doctors as they wanted to become

10 Board certified.

11 Q Were you on the editorial board of *Obstetrics*

12 *and Gynecology*?

13 A Yes.

14 Q What does it mean to be on the editorial board

15 of a medical journal?

16 A I was more active as a peer reviewer for that

17 journal. So instead of receiving a manuscript maybe

18 every month or every other month, I was assigned

19 five to ten per month where I would review them, and

20 we would meet annually as a group as the editorial

21 board, similar to the role of board of directors, to

22 see what the future of the journal should be and how

23 we could get it to that point.

24 Q In your surgical practice, did you utilize

25 mesh for certain procedures?

1 (Weber - Direct) Page 235

2 A Yes.

3 Q Did you use sutures for certain procedures?

4 A Yes.

5 Q Did you treat prolapse on a regular basis

6 surgically?

7 A Yes.

8 Q Are you familiar with the various procedures

9 that are at issue in this case?

10 A Yes.

11 MR. SLATER: Your Honor, at this time

12 we would offer Dr. Weber as an expert in the

13 field of urogynecology?

14 THE COURT: Are there any questions on

15 qualifications?

16 MS. ROBINSON: No, Your Honor.

17 THE COURT: Okay, ladies and gentlemen,

18 the witness is qualified to provide expert

19 opinion testimony in her fields of expertise.

20 Proceed.

21 - - -

22 DIRECT EXAMINATION

23 - - -

24 BY MR. SLATER:

25 Q Doctor, do you understand that any opinion you

1 (Weber - Direct) Page 236

2 offer in this case must be to a reasonable degree of

3 medical certainty?

4 A Yes.

5 THE COURT: Before we go further, are

6 you offering into evidence her CV?

7 MR. SLATER: Not at this time, Your

8 Honor.

9 THE COURT: Fine. Fair enough.

10 Q So, Doctor, if you offer us an opinion we are

11 going to understand it's to reasonable degree of

12 medical certainty unless you tell us otherwise. Do

13 you understand that?

14 A Yes.

15 Q Now, for the work you have done in this case,

16 the case we are in court for, have you been paid for

17 the time you've spent?

18 A Yes.

19 Q And have you issued invoices for and/or plan

20 to issue further invoices for work you have done in

21 more recent time?

22 A Yes.

23 Q And are you going to be paid for the time you

24 spend in this courtroom?

25 A Yes.

1 (Weber - Direct) Page 237

2 Q And what do you charge to come to court like

3 this for a jury?

4 A Courtroom testimony, I have a charge of \$1,000

5 per hour.

6 Q Now let's put up, we have a PowerPoint of

7 materials you have reviewed. Let's put that up.

8 Doctor, this List of Materials

9 Reviewed, what is that, simple terms?

10 A So this is a list of the kinds of materials I

11 have reviewed in the course of my work with

12 Mr. Slater.

13 Q Did you estimate the number of pages of

14 documents from Ethicon and medical literature and

15 clinical study, Doctor, is there any way to estimate

16 the volume of documents you have looked at?

17 A We have made an estimate of over one million

18 pages of documents.

19 Q And your review of these materials, are these

20 materials you intend to rely on in offering your

21 opinions here today?

22 A Yes.

23 Q And I will just read it for the record:

24 Medical literature, clinical and preclinical

25 studies, including underlying data, Ethicon/Johnson

1 (Weber - Direct) Page 238

2 & Johnson internal documents?

3 THE COURT: Well, we can read it. Is

4 that what you relied on?

5 THE WITNESS: Yes.

6 THE COURT: Okay, next question. You

7 can keep it up as long as you would like.

8 Q I am ready to go to the next line, Treatment

9 Options.

10 Doctor, we have a slide up here,

11 Treatment Options. Can you tell us what this

12 represents?

13 A So there are many options for treating women

14 with prolapse, which depends entirely on their

15 symptoms.

16 Q And just going through them very quickly, what

17 is each?

18 A So the first represents observation, which is

19 watchful waiting. This is not a dangerous

20 condition, not something that changes quickly. If a

21 woman is not symptomatic or only minimally

22 symptomatic, this is a perfectly reasonable option.

23 Q Pessary, we have heard about so we are going

24 to skip that.

25 Suture repair, just very briefly, what

1 (Weber - Direct) Page 239

2 are we talking about?

3 A Suture repair, colporrhaphy is the medical

4 term for suture repair, either in the front wall or

5 the back wall of the vagina, where sutures are used

6 to bring the tissue together and strengthen the wall

7 of the vagina.

8 Q And abdominal sacrocolpopexy, we heard what

9 that is, just one sentence or so to show you know

10 what it is?

11 A A procedure that lifts the top of the vagina

12 and using another type of material attaches it to

13 the back of the tailbone in order to provide

14 support.

15 Q The suture repairs and the abdominal

16 sacrocolpopexy, did you perform those routinely in

17 your practice?

18 A Yes.

19 Q Next, biologic or synthetic graft augmented

20 repair. What are we talking about there?

21 A So using another type of material, biologic

22 may be something like cadaveric fascia or other

23 products that are developed from animals where they

24 are in a layer that can be used to help support the

25 organs. And synthetic in the same way except,

1 (Weber - Direct) Page 240

2 obviously, that's something that's manmade.

3 Q Did you perform procedures with those

4 techniques?

5 A Rarely.

6 Q Mesh kit, something like the Prolift. Now I

7 understand the Prolift came on the market after you

8 stopped operating on patients, correct?

9 A Yes.

10 Q Are you familiar with the Prolift and the mesh

11 material?

12 A Yes.

13 Q Are you familiar with the procedure, the

14 instruments, how it's performed?

15 A Yes.

16 Q Have you reviewed surgical videos, their

17 surgical documents, their internal documents on how

18 it's to be done?

19 A Yes.

20 Q Doctor, with regard, and I am only going ask

21 this question one time just to situate, do you have

22 an opinion as to whether suture repair and/or

23 abdominal sacrocolpopexy would have been a safer

24 alternative than the Prolift for her treatment?

25 A Yes.

1 (Weber - Direct) Page 241

2 Q And very simply, why is that?

3 A Because either of those types of procedures

4 would have been successful in resolving her symptoms

5 without introducing the set of complications which

6 she has developed.

7 Q The synthetic graft augmented repair -- I am

8 not going to go into that. Let's go to the slide

9 now P1660.

10 Doctor, this PowerPoint, are you

11 familiar with this?

12 A Yes.

13 Q And LIGHTning, what is LIGHTning.

14 A I am sorry?

15 Q Right on the front it says LIGHTning. What is

16 project LIGHTning?

17 A It was Ethicon's code word for the development

18 of a new product after Prolift.

19 Q What was that ultimately called?

20 A That was Prolift Plus M.

21 Q And this PowerPoint is by Peter Meier, he was

22 a scientist at Ethicon.

23 A Yes.

24 Q And what is the date on the top right?

25 A September 6, 2006.

1 (Weber - Direct) Page 242

2 Q What I would like to turn you to now is page

3 14, and the pages are numbered.

4 Is this PowerPoint something you relied

5 on in forming your opinions in this case?

6 A Yes.

7 Q And we have here on the screen, it says a,

8 Human Cadaver Wet Lab was performed with Dr. Kurt

9 Lobodasch. What does that mean, a cadaver lab?

10 A A cadaver lab is where cadavers are set up in

11 a laboratory where they are positioned in such a way

12 they can be used for testing whatever it is that you

13 want to be testing.

14 Q And here it says, "There was a successful

15 cadaver lab with Dr. Lobodasch." Do you see that?

16 A Yes.

17 Q I am going to ask you a couple of things and

18 ask if they are significant. The first two,

19 "Preferred Ultrapro over Gynemesh PS." Is that

20 significant to you?

21 A Yes.

22 Q Very simply, what is Ultrapro?

23 A Ultrapro is an Ethicon mesh that is partially

24 absorbable and partially permanent polypropylene.

25 Q And the Gynemesh PS is what?

1 (Weber - Direct) Page 243

2 A Is the permanent polypropylene mesh in the

3 Prolift.

4 Q He says, "Better handling of Ultrapro with

5 Prolift instruments," is that significant to you?

6 A Yes.

7 Q Why is that?

8 A This doctor is expressing that the handling,

9 just the hand feel and how he is able to work with

10 the Ultrapro mesh with instruments is better than

11 what he was experiencing with the Gynemesh.

12 Q And a little further down it says, "Feels very

13 soft in place." Is that significant?

14 A Yes.

15 Q Why is that?

16 A If he says the Ultrapro is very soft, then by

17 comparison the Gynemesh must be less soft.

18 Q Why is that significant in a pelvic floor

19 treatment?

20 A Ideally, that would correspond to how the mesh

21 behaves in the woman.

22 Q It says, "No crumpling of arms compared to

23 Gynemesh PS." And those arrows, they are on the

24 document, right?

25 A Yes.

1 (Weber - Direct) Page 244

2 Q Is that significant to you?

3 A Yes.

4 Q Why is that significant?

5 A As you can see, the crumpling of the arms with

6 the Gynemesh PS, this is exactly what happens in

7 person. And I know you have seen the videos where

8 you have see the roping of the mesh arms and the

9 complications that occur as a result of that. The

10 Ultrapro does not have that appearance and ideally,

11 it would not have that behavior as the Gynemesh PS

12 showed.

13 Q What if any significance is there to the arm

14 crumpling or roping in the body of an actual

15 patient, what does that do?

16 A So when the mesh is crumpled, that increases

17 the amount of mesh in that area. And the more the

18 mesh is bunched up together, that increases the

19 inflammation, the foreign body reaction, the pores

20 are scrunched down so that the tissue can't grow in

21 there as it's intended to do. Instead, it forms

22 this fibrotic ridging, scar plating that turns the

23 mesh into this rock-hard, caked piece of tissue and

24 mesh instead of something where the tissue has been

25 able to lay flat along with the mesh and not cause



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1

2 **so many complications.**

3 Q And that issue that you just described, the

4 crumpling, the bunching of mesh, is that something

5 that Ethicon was knowledgeable about based on your

6 review of the materials?

7 **A Yes.**

8 Q And even at this time, as of September 2006?

9 **A Yes.**

10 Q And then it stays, "Near to my expectation of

11 replacing pelvic floor tissue." Is that

12 significant?

13 **A Yes.**

14 Q Why is that?

15 **A The idea of putting mesh in the vagina was to**

16 **reproduce the normal tissue, and the problem is that**

17 **a hernia mesh that Ethicon took and transposed into**

18 **Gynemesh PS, the exact same mesh, was not behaving**

19 **in the vagina in a way that was anything like normal**

20 **vaginal tissue. And the hope was within Ethicon**

21 **that the Ultrapro would do a better job of acting**

22 **like the normal vaginal tissue.**

23 Q Let's go down to page 22. This is talking

24 about in vitro testing. That would be lab testing

25 of the Ultrapro?

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1

2 **A Yes.**

3 Q Is that something Ethicon relied upon in the

4 business to evaluate meshes?

5 **A Yes.**

6 Q And the third bullet point says, "Area weight

7 (lightness) that Ultrapro is lighter than Gynemesh,

8 Vypro and most competitors." Is the lightness of

9 the mesh significant?

10 **A It can be, yes.**

11 Q Why is that?

12 **A So by lightness they are referring to**

13 **basically the amount of mesh, and theoretically, it**

14 **would be best for the woman to have less mesh**

15 **remaining in her body.**

16 Q Why is that?

17 **A Because the more mesh there is, it becomes a**

18 **cascade of the inflammatory reaction or body**

19 **reaction, the scar plating and bridging fibrosis,**

20 **that leads to all kinds of other complications, mesh**

21 **erosion, vaginal anatomic distortion, and, you know,**

22 **the woman experiences dyspareunia and pelvic pain,**

23 **and just turns into a vicious cycle where the more**

24 **mesh there is, it's like feeding wood to a fire.**

25 Q It says, Pore Size. "Ultrapro has larger pore

(Weber - Direct) Page 247

1

2 size than Gynemesh PS, 3 to 5 millimeters compared

3 to 0.3 to 2.4 millimeters." Is that significant?

4 **A Yes.**

5 Q And when they are talking about these pore

6 sizes they are talking about the mesh before it's

7 been put in the body, right?

8 **A Yes.**

9 Q Why is the pore size significant and what's

10 the difference between before it goes into the body

11 and when it goes into the body, what's the issue

12 there?

13 **A The pore size is significant because it's been**

14 **established that the pores have to remain in a**

15 **diameter of one millimeter in all directions to**

16 **avoid this phenomenon of the fibrotic bridging.**

17 **When the pores are smaller than that, it's easier**

18 **for the body's tissues, the collagen and whatnot, to**

19 **grow across the mesh and pull it together and cause**

20 **the mesh shrinkage and then all the things that we**

21 **have already been talking about.**

22 Q Do you have an opinion as to whether the

23 Prolift+M with the Ultrapro mesh was a safer

24 alternative to the Prolift?

25 **A Yes.**

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1

2 Q What is that opinion?

3 **A It was safer.**

4 Q Why is that?

5 **A Because it was lighter and left less mesh in a**

6 **woman after the absorbable part went away, and**

7 **because, at least in theory and before it got placed**

8 **in a woman, the pore sizes were larger and would**

9 **able to avoid this phenomenon of the fibrotic**

10 **bridging, et cetera, et cetera.**

11 Q Doctor, I have given you a large document that

12 I promise we are only going to go through a little

13 bit of. This is Exhibit P625, and this is -- first

14 of all, there is an E-mail, November 1st, 2010, from

15 Peter Meier, enclosing the updated report on erosion

16 of meshes. Correct?

17 **A Yes.**

18 Q And this is the same Peter Meier who authored

19 that PowerPoint we just saw with the jury?

20 **A Yes.**

21 Q Let's turn to the actual first page of the

22 report and just show that to the jury so they can

23 see the front page. And it shows, September 13,

24 2010, Clinical Evaluation Report, Mesh Erosions, by

25 Peter Meier, Principal Scientist at Johnson &



<p>1 (Weber - Direct) Page 249</p> <p>2 Johnson Medical. Correct?</p> <p>3 <b>A Yes.</b></p> <p>4 Q What I would like to now is first ask you,</p> <p>5 Charlotte Owens who is the Medical Director, did she</p> <p>6 testify as to whether or not she was aware of those</p> <p>7 complications and issues we are going to discuss</p> <p>8 now?</p> <p>9 <b>A Yes.</b></p> <p>10 Q Did she say she knew about those before the</p> <p>11 Prolift was launched?</p> <p>12 <b>A Yes.</b></p> <p>13 Q Let's go to Section 2.2, which is on page</p> <p>14 seven. If we go down to the second paragraph, the</p> <p>15 second sentence --</p> <p>16 MR. SLATER: If it's okay, Your Honor,</p> <p>17 I would like to read it and ask the expert if</p> <p>18 she has an opinion about it.</p> <p>19 THE COURT: Let's try it fresh and then</p> <p>20 we will see how it turns out.</p> <p>21 Q The second sentence, "Mesh material-related</p> <p>22 adverse events included infections, erosions</p> <p>23 extrusions, mesh shrinkage, vaginal granulation</p> <p>24 tissue, sinus formation, abscesses, fistulas,</p> <p>25 osteomyelitis."</p>	<p>1 (Weber - Direct) Page 251</p> <p>2 they are significant to her. It's not a</p> <p>3 proper way to ask an expert questions.</p> <p>4 THE COURT: (Direct to the Jury:)</p> <p>5 Ladies and gentlemen of the jury, we are going</p> <p>6 to break at this time while I deal with this</p> <p>7 objection. I will ask you to return tomorrow</p> <p>8 at 9:30. Between now and when you return,</p> <p>9 keep an open mind and don't discuss the case</p> <p>10 with anyone. Is it too late to remind you not</p> <p>11 to discuss the case with anyone? Please don't</p> <p>12 discuss the case with anyone.</p> <p>13 Bring the jury out.</p> <p>14 (The jury is excused from the courtroom</p> <p>15 at 4:33 p.m.)</p> <p>16 THE COURT: I will see counsel in</p> <p>17 Chambers on the record.</p> <p>18 (The following transpired in the robing</p> <p>19 room with counsel present:)</p> <p>20 THE COURT: Okay, what's the problem?</p> <p>21 MS. ROBINSON: Your Honor, I have been</p> <p>22 fairly patient with counsel just putting</p> <p>23 documents up in front of the witness, reading</p> <p>24 them to her and asking then if that particular</p> <p>25 part is significant to her. I think the</p>
<p>1 (Weber - Direct) Page 250</p> <p>2 I am going to stop there. Is that</p> <p>3 information significant to you?</p> <p>4 <b>A Yes.</b></p> <p>5 Q And I neglected to ask, is this entire report</p> <p>6 something you relied on in forming your opinions?</p> <p>7 <b>A Yes.</b></p> <p>8 Q Are you familiar with this document?</p> <p>9 <b>A Yes.</b></p> <p>10 Q Why is that sentence significant to you?</p> <p>11 <b>A That is significant because it lists just some</b></p> <p>12 <b>of the extremely serious complications that can</b></p> <p>13 <b>occur after the implantation of this permanent mesh</b></p> <p>14 <b>that are directly related to the mesh</b></p> <p>15 <b>characteristics itself.</b></p> <p>16 Q Now let's go to Page 8, Section 3 titled,</p> <p>17 Etiology of Mesh Erosions, the first paragraph. It</p> <p>18 says "Erosion means superficial --</p> <p>19 MS. ROBINSON: Objection.</p> <p>20 THE COURT: I will see you at sidebar.</p> <p>21 (The following transpired at sidebar:)</p> <p>22 THE COURT: What's your objection?</p> <p>23 MS. ROBINSON: Your Honor, I am</p> <p>24 objecting to him just throwing up slides and</p> <p>25 reading them to the witness and asking him if</p>	<p>1 (Weber - Direct) Page 252</p> <p>2 appropriate way to examine her is to show her</p> <p>3 the document, say what about the document did</p> <p>4 you use to rely upon to form your opinions.</p> <p>5 MR. SLATER: Your Honor, I think that</p> <p>6 there is nothing wrong with identifying a</p> <p>7 portion of a 122-page document, the portions</p> <p>8 that we believe are significant, identifying</p> <p>9 them for the jury and then, whether I read</p> <p>10 them or the expert reads them, letting the</p> <p>11 jury know what is at issue and then letting</p> <p>12 the expert provide the opinion, which is the</p> <p>13 significant part of it, so that there is an</p> <p>14 opinion linked to a foundation, rather than</p> <p>15 having the expert just speak. She may not</p> <p>16 talk about the parts I want to address and we</p> <p>17 have to go round and round.</p> <p>18 THE COURT: In other words, you have to</p> <p>19 lead her.</p> <p>20 MR. SLATER: Sort of lead her.</p> <p>21 THE COURT: The objection is sustained.</p> <p>22 Is there anything else we can</p> <p>23 accomplish today?</p> <p>24 MS. ROBINSON: Your Honor, I do want to</p> <p>25 raise once again the witness' intent to go</p>

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1 through the Lucente database. There is a

2 number of things wrong with it, I think in

3 terms of, one, it's not relevant and it's

4 highly prejudicial. This database isn't a

5 database that Ethicon owned, it's not

6 information that Ethicon was provided. It is

7 highly unreliable because --

8 THE COURT: Wait a minute, it's highly

9 unreliable?

10 MS. ROBINSON: Yes.

11 THE COURT: Can you demonstrate that?

12 MS. ROBINSON: The two investigators --

13 THE COURT: Can you demonstrate that

14 it's highly unreliable? Is that just lawyer

15 talk?

16 MS. ROBINSON: It's maybe hyperbole

17 but --

18 THE COURT: Well, then let's stick to

19 what you can demonstrate. All right? Your

20 hyperbole is stricken from the record as not

21 something that will ever be supported by the

22 evidence. So let's stick to what the evidence

23 will show.

24 MS. ROBINSON: The Lucente database,

25

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1 Your Honor, is a retrospective study that

2 Vincent Lucente started along with his partner

3 Dr. Murphy, and they obtained a grant, a

4 \$12,500 grant from Ethicon. The data was data

5 that they already had in their practice in

6 patients that they had operated on. As a part

7 of this grant they were to put together a

8 retrospective study of their patients and

9 eventually publish it. They never published

10 it and didn't get the last payment from

11 Ethicon for that.

12 The data was owned by Lucente and his

13 facility. Ethicon had the right to inspect it

14 at points in time if they desired. The data

15 is -- the witnesses will testify and have

16 probably testified that there are a number of

17 different patients. So the data that was

18 provided --

19 THE COURT: Can we get back to what is

20 objectionable about it?

21 MS. ROBINSON: It's completely

22 unreliable.

23 THE COURT: Can you demonstrate that?

24 MS. ROBINSON: Walking through a number

25

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1 of different hoops.

2 THE COURT: However many days you need,

3 can you demonstrate in cross-examination of

4 anybody who relies on this database that they

5 don't know what they are talking about or they

6 are relying on something that's unreliable?

7 MS. ROBINSON: It was never complete,

8 and I think the burden --

9 THE COURT: Does that mean the answer

10 is yes or no?

11 MS. ROBINSON: The answer is yes.

12 THE COURT: Okay. Then you will

13 demonstrate that this person is nothing more

14 than a paid professional witness, relying on

15 things that are demonstrably unreliable. The

16 objection is once again overruled.

17 Is there anything else we can

18 accomplish today?

19 MR. SLATER: Just to avoid anything

20 tomorrow, based on Your Honor's ruling, my

21 intention would be to at least draw

22 Dr. Weber's attention to specific paragraphs.

23 THE COURT: Okay. Would you object to

24 that?

25

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1 MS. ROBINSON: I think it depends on

2 how it proceeds.

3 THE COURT: How it proceeds? It's

4 going to proceed exactly the way it proceeded

5 today. Are you going to object to that?

6 MS. ROBINSON: If it proceeds exactly

7 the way it proceeded today, yes, Your Honor.

8 THE COURT: That will be sustained,

9 too.

10 MR. SLATER: If I say, I just want you

11 to look at this paragraph, ask her what it is

12 talking about, and let her testify how it

13 matters to her?

14 THE COURT: What opinions is she going

15 to offer?

16 MR. SLATER: She is going to offer

17 opinions about the mesh, about the

18 involvement --

19 THE COURT: Why don't you start with

20 the opinions, but I am not going to tell you

21 how to do whatever you want to do. But to me,

22 so far, this is just totally floating in the

23 ether.

24 Anything further?

25

1                               **(Weber - Direct)**                               Page 257  
2                               MS. ROBINSON: No, Your Honor, thank  
3                               you.  
4                               THE COURT: See you tomorrow morning at  
5                               9:30.  
6                               - - -  
7                               (Hearing is adjourned at 4:35 p.m.)  
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1                               **(Weber - Direct)**                               Page 258  
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3  
4                               I HEREBY CERTIFY THAT THE PROCEEDINGS  
5                               AND EVIDENCE ARE CONTAINED FULLY AND ACCURATELY IN  
6                               THE NOTES TAKEN BY ME ON THE TRIAL OF THE ABOVE  
7                               CAUSE, AND THAT THIS COPY IS A CORRECT TRANSCRIPT OF  
8                               THE SAME.  
9  
10                              JUDITH ANN ROMANO, RPR-CM-CRR  
11                              OFFICIAL COURT REPORTER  
12                              COURT OF COMMON PLEAS  
13                              PHILADELPHIA COUNTY  
14                              THE FOREGOING CERTIFICATION OF THIS  
15                              TRANSCRIPT DOES NOT APPLY TO ANY REPRODUCTION OF THE  
16                              SAME BY ANY MEANS UNLESS UNDER THE DIRECT CONTROL  
17                              AND/OR DIRECTION OF THE CERTIFYING COURT REPORTER.  
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*Hammons v.  
Ethicon, et al.*

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*John J. Kurz, RMR, CRR, Official Court Reporter  
City of Philadelphia  
First Judicial District Of Pennsylvania  
100 South Broad Street, 2nd Floor  
Philadelphia, PA 19110*

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Hammons v. Ethicon, et al.

<p>1 IN THE COURT OF COMMON PLEAS OF PHILADELPHIA COUNTY 2 FIRST JUDICIAL DISTRICT OF PENNSYLVANIA 3 CIVIL TRIAL DIVISION</p> <p>4 IN RE: PELVIC MESH LITIGATION :</p> <p>5 PATRICIA HAMMONS, : MAY TERM, 2013 6 Plaintiff : 7 : 8 v. : 9 ETHICON, INC., et al., : NO. 3913 10 Defendants : 11 12 TUESDAY, DECEMBER 8, 2015 13 14 COURTROOM 246 15 CITY HALL 16 PHILADELPHIA, PENNSYLVANIA 17 18 B E F O R E: THE HONORABLE MARK I. BERNSTEIN, J., 19 and a Jury 20 21 JURY TRIAL - VOLUME VI 22 23 MORNING SESSION 24 25 REPORTED BY: JOHN J. KURZ, RMR, CRR REGISTERED MERIT REPORTER CERTIFIED REALTIME REPORTER OFFICIAL COURT REPORTER</p>	<p>- HAMMONS -vs- ETHICON, et al. - Page 3</p> <p>1 A P P E A R A N C E S: (Continued) 2 3 GOLDMAN, ISMAIL, TOMASELLI, BRENNAN &amp; BAUM, LLP 4 BY: TAREK ISMAIL, ESQUIRE (admitted pro hac vice) 5 564 West Randolph Street, Suite 400 Chicago, Illinois 60661 6 T: 312-681-6000 F: 312-881-5190 E-mail: tismail@goldmanismail.com 7 Counsel for Defendants Ethicon and Johnson &amp; 8 Johnson 9 10 THOMAS COMBS &amp; SPANN, PLLC 11 BY: SUSAN M. ROBINSON, ESQUIRE (admitted pro hac vice) 12 300 Summers Street, Suite 1380 Charlestown, WV 25338 13 T: 304-414-1800 F: 304-414-1801 14 Counsel for Defendants Ethicon and Johnson &amp; 15 Johnson 16 17 Also Present: 18 Charles Tasco, Court Crier 19 20 21 22 23 24 25</p>
<p>- HAMMONS -vs- ETHICON, et al. - Page 2</p> <p>1 A P P E A R A N C E S: 2 KLINE &amp; SPECTER, A Professional Corporation 3 BY: SHANIN SPECTER, ESQUIRE BY: KILA B. BALDWIN, J.D., ESQUIRE 4 1525 Locust Street The Nineteenth Floor Philadelphia, Pennsylvania 19102 5 T: 215-772-1000 F: 215-735-0937 E-mail: shanin.specter@klinespecter.com 6 kila.baldwin@klinespecter.com Counsel for Plaintiff Hammons 7 8 9 MAZIE, SLATER, KATZ &amp; FREEMAN 10 BY: ADAM M. SLATER, ESQUIRE 103 Eisenhower Parkway Roseland, New Jersey 07068 11 T: 973-228-0454 F: 973-228-0303 E-mail: aslater@mskf.net 12 Counsel for Plaintiff Hammons 13 14 15 DRINKER BIDDLE &amp; REATH, LLP 16 BY: MOLLY E. FLYNN, ESQUIRE One Logan Square, Suite 2000 Philadelphia, Pennsylvania 19103-6996 17 T: 215-988-2836 F: 215-988-2757 E-mail: molly.flynn@dbrr.com 18 Counsel for Defendants Ethicon and Johnson &amp; 19 Johnson 20 21 TUCKER ELLIS, LLP 22 BY: MATTHEW P. MORIARTY, ESQUIRE 950 Main Avenue, Suite 1100 Cleveland, Ohio 44113-7213 23 T: 216-696-2276 F: 216-592-5009 E-mail: matthew.moriarty@tuckerellis.com 24 Counsel for Defendants Ethicon and Johnson &amp; 25 Johnson</p>	<p>- HAMMONS -vs- ETHICON, et al. - Page 4</p> <p>1 - I N D E X - 2 WITNESSES VD DR CR RD RC 3 ANNE M. WEBER, M.D. 4 By Mr. Slater -- 19 -- -- 5 By Ms. Robinson -- -- 100 -- -- 6 7 8 9 E X H I B I T S 10 N O. P A G E N O. 11 P-1666 Abstract 19 12 P-1754 French TVM Study 38 13 P-1735 TVM Study, Primary Endpoint 43 14 P-1737 TVM Study Mesh Exposure Rate 45 15 PLT-0227 medical article 47 16 P-3196 Research funding agreement 49 17 P-3215 e-mail with abstract 2009 52 18 P-2137 Clinical Expert Report Jan 2005 61 19 PLT-0629 abstract from TVM group 73 20 PLT-0089 article from TVM group 73 21 P-1499 abstract from French TVM group 75 22 P-2640 PowerPoint from meeting in Paris on September 29, 2003 77 23 24 PLT-0489 medical article-ultrasound 79 25 P-1706 IUGA meeting slide 83</p>



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<p>1 - I N D E X - (Continued)</p> <p>2 E X H I B I T S</p> <p>3 N O. P A G E N O.</p> <p>4 PLT-0151 article, systematic review 85</p> <p>5 PLT-0011 Practice Bulletin 87</p> <p>6 PLT-0506 letter to editor of IUG 93</p> <p>7</p> <p>8</p> <p>9</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>		<p>1 the transcript in context --</p> <p>2 THE COURT: What page?</p> <p>3 MR. ISMAIL: So the question and</p> <p>4 answer was -- the first one is at Page 240, Line</p> <p>5 20.</p> <p>6 I have a copy.</p> <p>7 THE COURT: I got it.</p> <p>8 MR. ISMAIL: Very good.</p> <p>9 THE COURT: Yeah. Any other?</p> <p>10 MR. ISMAIL: And then the follow-up</p> <p>11 question onto Page 241, "And very simply, why is</p> <p>12 that?"</p> <p>13 And then the witness volunteers her</p> <p>14 symptoms in the answer.</p> <p>15 THE COURT: Yeah. Yeah.</p> <p>16 And she also put up -- or counsel put</p> <p>17 up that she confirmed a list of everything that</p> <p>18 she had reviewed. Were there any medical</p> <p>19 records of Ms. Hammons --</p> <p>20 MR. SLATER: Yes.</p> <p>21 THE COURT: -- on that list?</p> <p>22 There were, okay.</p> <p>23 You did not mention that in your</p> <p>24 offer of proof, correct?</p> <p>25 MR. SLATER: I'm going to try to find</p>	
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<p>1 PROCEEDINGS</p> <p>2 (Time: 9:45 a.m.; Morning Session.)</p> <p>3 - - -</p> <p>4 (The following transpired in open</p> <p>5 court outside the presence of the jury:)</p> <p>6 - - -</p> <p>7 THE COURT: Is there anything we can</p> <p>8 accomplish now?</p> <p>9 MR. ISMAIL: One issue we'd like to</p> <p>10 address, Your Honor.</p> <p>11 THE COURT: Yes, sir.</p> <p>12 MR. ISMAIL: This relates to the</p> <p>13 testimony of Dr. Weber. In the proffer that</p> <p>14 counsel made to the Court, there was a specific</p> <p>15 exchange as to whether or not Dr. Weber would</p> <p>16 address Mrs. Hammons.</p> <p>17 THE COURT: Yes.</p> <p>18 MR. ISMAIL: And there was a</p> <p>19 representation that there was no such testimony</p> <p>20 expected from Dr. Weber.</p> <p>21 THE COURT: Yes.</p> <p>22 MR. ISMAIL: Upon reviewing the</p> <p>23 transcript last night, there was a question --</p> <p>24 two questions and answers which used the pronoun</p> <p>25 "her" rather than Ms. Hammons. But in reviewing</p>		<p>1 the exact words, Your Honor.</p> <p>2 THE COURT: Fine. Good.</p> <p>3 MR. SLATER: When I talked about</p> <p>4 it --</p> <p>5 THE COURT: Wait. If you're going to</p> <p>6 try to find the exact words, then we'll wait.</p> <p>7 MR. ISMAIL: May I?</p> <p>8 THE COURT: May you what?</p> <p>9 MR. ISMAIL: Show you his exact</p> <p>10 words.</p> <p>11 THE COURT: Yeah. That would be</p> <p>12 great. Where is his exact words?</p> <p>13 MR. ISMAIL: Page 209.</p> <p>14 MR. SLATER: Is this the proffer?</p> <p>15 MR. ISMAIL: This is the proffer.</p> <p>16 THE COURT: 209.</p> <p>17 MR. ISMAIL: And at Line 18, Your</p> <p>18 Honor asked the question, and the response is</p> <p>19 given at Line 22.</p> <p>20 THE COURT: "I do not intend to</p> <p>21 elicit any opinions specific to the plaintiff."</p> <p>22 Was that another mistake, Mr. Slater?</p> <p>23 MR. SLATER: Your Honor, the two</p> <p>24 things that happened yesterday were, number one,</p> <p>25 the materials reviewed, as I learned with</p>	

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<p>- HAMMONS -vs- ETHICON, et al. - Page 9</p> <p>1 Dr. Elliott, the full amount of things she 2 reviewed should be there so that it's understood 3 what she saw. I didn't want her to then be 4 cross-examined, hey, you didn't tell us you saw 5 these things. 6 The issue with the alternative 7 procedures is simply this: I couldn't ask the 8 question, I didn't think, logically without 9 placing it in the context of the patient; that 10 these were alternatives available that would be 11 reasonable for her. That's it. 12 <b>THE COURT:</b> What's it? 13 <b>MR. SLATER:</b> That's all I did. I 14 didn't think there was any other way to place 15 it -- to put it in without an appropriate 16 context. 17 <b>THE COURT:</b> So this was not a second 18 mistake. This was an intentional asking about 19 her after having said in your offer of proof 20 that you don't intend to elicit anything 21 specific to her; is that what you're telling me? 22 <b>MR. SLATER:</b> I -- I -- I don't see it 23 as a intentional violation of anything. I 24 wasn't trying to violate anything. I made the 25 proffer as best I could, Your Honor.</p>	<p>- HAMMONS -vs- ETHICON, et al. - Page 11</p> <p>1 was talking about. That's what I intended to 2 convey; that we weren't going to go through her 3 medical course, say this was caused by this, 4 that was caused by that. I wasn't going to get 5 into it and we're not going to. That was what I 6 intended to convey, Your Honor. 7 And if the issue of the proffer was 8 whether she was qualified, she certainly is 9 qualified to have said these were safe 10 alternatives for this patient. 11 <b>THE COURT:</b> So, "I do not intend to 12 elicit any opinions specific to plaintiff." Any 13 means what? 14 What does the word "any" mean in that 15 context? 16 <b>MR. SLATER:</b> I understand what it 17 means, Your Honor. 18 <b>THE COURT:</b> What does it mean? 19 Because maybe we're using a common word to mean 20 two different things. 21 <b>MR. SLATER:</b> My intention was talking 22 about -- 23 <b>THE COURT:</b> No. What does the word 24 "any" mean in that sentence? 25 <b>MR. SLATER:</b> I assume it means any.</p>
<p>- HAMMONS -vs- ETHICON, et al. - Page 10</p> <p>1 <b>THE COURT:</b> No. I don't know about 2 violate. But it was inconsistent, intentionally 3 inconsistent with what you had said at the 4 proffer, right? 5 <b>MR. SLATER:</b> I didn't know how else 6 to make it relevant, Your Honor. 7 <b>THE COURT:</b> "I didn't know how else," 8 which means that I've thought about it and I 9 decided that this is how I should do it even 10 though in the proffer I had said the exact 11 opposite; is that what you mean? 12 <b>MR. SLATER:</b> I don't believe that I 13 mean that I intentionally did anything, Your 14 Honor. 15 <b>THE COURT:</b> Okay. So then how could 16 it happen that on a proffer you specifically say 17 I don't intend and then 60 pages later you ask 18 the exact question? 19 <b>MR. SLATER:</b> When I talked about -- 20 <b>THE COURT:</b> It's not a mistake and 21 it's not intentional. Tell me what it is, then. 22 <b>MR. SLATER:</b> What I intended when I 23 talked about Ms. Hammons was that we weren't 24 going to ask causation questions or about what 25 happened to her due to the mesh. That's what I</p>	<p>- HAMMONS -vs- ETHICON, et al. - Page 12</p> <p>1 I don't have a definition. 2 <b>THE COURT:</b> You can't define -- no 3 definition of the word "any." 4 <b>MR. SLATER:</b> I think "any" has a 5 common, understood term. I'm not disputing -- 6 <b>THE COURT:</b> And what is your commonly 7 understood term? 8 <b>MR. SLATER:</b> Any means none. 9 <b>THE COURT:</b> "None." 10 <b>MR. SLATER:</b> But I was intending to 11 convey causation opinions, which was I thought 12 what they were concerned about from the 13 conversation. 14 I was rushing through this. I went 15 as quickly as I could, but that's what I 16 intended to convey. And, again, the proffer was 17 for purposes of them to object to her testimony. 18 There was no legitimate objection to her 19 qualifications. 20 <b>THE COURT:</b> No. The proffer -- I 21 don't know what you thought the proffer was for. 22 I don't read minds, but the proffer was so that 23 you could tell opposing counsel what of the 24 500-plus pages of her report they had to expect 25 in testimony. Because it would be improper, in</p>



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<p>- HAMMONS -vs- ETHICON, et al. - Page 13</p> <p>1 my opinion, to force counsel to expect anything 2 in an overly inclusive, obviously huge amount of 3 paper. 4 Yes. So what flows from this, 5 Counsel? 6 <b>MR. ISMAIL:</b> Your Honor, what flows 7 from this, we think the question and answer 8 should be stricken from the record. The jury 9 should be instructed that Dr. Weber is not 10 offering any opinions and her testimony is not 11 as to Mrs. Hammons. 12 And I'll point out, Your Honor, that 13 the second question, Dr. Weber volunteered the 14 very causation opinion -- 15 <b>THE COURT:</b> Remind me what page it 16 is. I didn't mark it. 17 <b>MR. ISMAIL:</b> 241, Line 3 is the 18 beginning of her answer. 19 <b>THE COURT:</b> That's not a causation 20 opinion. 21 <b>MR. ISMAIL:</b> "Without introducing the 22 set of complications she has developed." 23 <b>THE COURT:</b> I don't think it's a 24 causation opinion. 25 So what do you want me to do? You</p>	<p>- HAMMONS -vs- ETHICON, et al. - Page 15</p> <p>1 <b>THE COURT:</b> Wait. As I believe, it 2 was the Court that said what's your proffer. 3 <b>MR. SLATER:</b> Yes, Your Honor. 4 <b>THE COURT:</b> And you didn't want to 5 tell them, give away your full direct 6 examination. And I think I said you don't have 7 to, but it makes their objection easy. 8 So do you want to address the remedy 9 that defense is asking for. 10 <b>MR. SLATER:</b> Yes, Your Honor. I 11 think that that remedy should not be imposed. 12 Dr. Weber's testimony is appropriate. It is -- 13 she's well-qualified to provide that opinion. 14 There was no -- again, there was no surprise to 15 them. They know she held that opinion. It's 16 very narrow on one narrow issue. They did not 17 object. I could have cured it at that point and 18 just said, okay, let's talk in general if they 19 objected to the mention of "her," and that's it. 20 I used one pronoun. I understand. I do not 21 dispute what Your Honor is saying. I'm telling 22 you what I sincerely believed when I told you 23 what I was going to do. There is no cause to 24 strike any testimony. The opinion's 25 appropriate. And they have no reasonable</p>
<p>- HAMMONS -vs- ETHICON, et al. - Page 14</p> <p>1 want me to read it to the jury and tell them to 2 disregard it? 3 <b>MR. ISMAIL:</b> I would like -- no, in 4 answer to your question, Your Honor. 5 We would like Your Honor to strike 6 Pages 240, Line 20, through 241, Line 6, and 7 that the jury should be instructed that 8 Dr. Weber does not -- is not offering any 9 opinions about Mrs. Hammons. 10 <b>THE COURT:</b> So can you tell me why 11 you didn't object when that happened. 12 <b>MR. ISMAIL:</b> Your Honor, the 13 question -- well, given the proffer, we weren't 14 expecting testimony about Mrs. Hammons. The 15 question didn't have Mrs. Hammons in the name -- 16 in the form of the question. Actually until we 17 went back and looked and saw the pronoun "she" 18 in the question and the answer did we realize 19 what had been elicited from the witness. 20 <b>THE COURT:</b> Okay. Mr. Slater, do you 21 wish to address that request? 22 <b>MR. SLATER:</b> Your Honor, we object to 23 that request. 24 The ultimate reason -- and I 25 understand that they wanted notice --</p>	<p>- HAMMONS -vs- ETHICON, et al. - Page 16</p> <p>1 objection to her qualification or that they were 2 not on notice that she had that opinion since 3 she's always held that opinion in this case. 4 <b>THE COURT:</b> Anything further? Is 5 there anything further? 6 Is there anything further? 7 <b>MR. ISMAIL:</b> No, Your Honor. 8 <b>THE COURT:</b> Okay. The testimony at 9 Page 240, Line 20, through 241, Line 6 is 10 stricken, and the Court will instruct the jury 11 about the limits of Ms. Hammons -- of 12 Ms. Weber's testimony; namely, that there will 13 be no specific opinions about Ms. Hammons 14 offered. 15 Is there anything further that we can 16 accomplish at this time? 17 <b>MR. SLATER:</b> No. 18 <b>MR. ISMAIL:</b> No, Your Honor. 19 <b>THE COURT:</b> Okay. We'll wait for the 20 juror. 21 (Pause in the proceedings.) 22 <b>THE COURT:</b> Charles is bringing in 23 the jury. 24 <b>MR. SLATER:</b> Judge, should I have 25 Dr. Weber go up first or wait till the jury is</p>

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<p>- HAMMONS -vs- ETHICON, et al. - Page 17</p> <p>1 seated?</p> <p>2 <b>THE COURT:</b> Hold on. No. You better</p> <p>3 wait.</p> <p>4 <b>COURT CRIER:</b> Please remain seated</p> <p>5 until the jury has reached the jury box.</p> <p>6 - - -</p> <p>7 (Whereupon the jury entered the</p> <p>8 courtroom at 10:01 a.m.)</p> <p>9 - - -</p> <p>10 (The following transpired in open</p> <p>11 court in the presence of the jury:)</p> <p>12 - - -</p> <p>13 <b>THE COURT:</b> Good morning, ladies and</p> <p>14 gentlemen.</p> <p>15 <b>JURY PANEL:</b> Good morning.</p> <p>16 (Witness resumed the witness stand.)</p> <p>17 <b>COURT CRIER:</b> Raise your right hand.</p> <p>18 Do you solemnly swear or if you affirm, do you</p> <p>19 affirm that you will answer every question</p> <p>20 truthfully?</p> <p>21 <b>THE WITNESS:</b> Yes.</p> <p>22 <b>COURT CRIER:</b> State your name for the</p> <p>23 record, please.</p> <p>24 <b>THE WITNESS:</b> Anne Margaret Weber.</p> <p>25 <b>COURT CRIER:</b> Spell your last name.</p>	<p>- ANNE M. WEBER - DIRECT - Page 19</p> <p>1 <b>BY MR. SLATER:</b></p> <p>2 <b>Q. Good morning, Dr. Weber.</b></p> <p>3 A. Good morning.</p> <p>4 <b>Q. Doctor, in order to speed things along, I've</b></p> <p>5 <b>stacked up a series of exhibits in front of you.</b></p> <p>6 <b>We'll go through them in order. I'm not going to</b></p> <p>7 <b>have to walk up and hand them to you, so I'll just</b></p> <p>8 <b>identify them as we go, okay?</b></p> <p>9 A. Yes.</p> <p>10 <b>Q. Okay. What I'd like to start out with is the</b></p> <p>11 <b>exhibit on the top of the pile, it's P-1666.</b></p> <p>12 <b>And is this a document you're</b></p> <p>13 <b>familiar with?</b></p> <p>14 A. Yes.</p> <p>15 <b>Q. Please tell the jury what that document is.</b></p> <p>16 A. This is an abstract that was presented at a</p> <p>17 scientific meeting representing results from one of</p> <p>18 the Ethicon-sponsored studies about the Gynemesh PS</p> <p>19 mesh.</p> <p>20 <b>Q. What was the name of that study?</b></p> <p>21 A. Gynemesh PS Mesh.</p> <p>22 <b>Q. Okay. And what was it that the doctors were</b></p> <p>23 <b>doing in that study?</b></p> <p>24 A. They were using the Gynemesh PS mesh in</p> <p>25 different prolapse operations, abdominally and</p>
<p>- HAMMONS -vs- ETHICON, et al. - Page 18</p> <p>1 <b>THE WITNESS:</b> W-E-B-E-R.</p> <p>2 <b>COURT CRIER:</b> Thank you. Please keep</p> <p>3 your voice up for the jury, please.</p> <p>4 <b>THE WITNESS:</b> Thank you.</p> <p>5 <b>THE COURT:</b> Ladies and gentlemen of</p> <p>6 the jury, yesterday you may have heard or</p> <p>7 understood some of the testimony to apply to a</p> <p>8 specific opinion concerning Ms. Hammons. This</p> <p>9 expert, Ms. Weber, has not been called to offer</p> <p>10 any opinions specifically about Ms. Hammons. So</p> <p>11 if you understood any testimony to refer</p> <p>12 specifically to Ms. Hammons, you are to</p> <p>13 disregard that testimony. It's stricken from</p> <p>14 the record.</p> <p>15 Are we ready to go?</p> <p>16 <b>MR. SLATER:</b> We are, Judge.</p> <p>17 <b>THE COURT:</b> Proceed.</p> <p>18 <b>MR. SLATER:</b> Thank you.</p> <p>19 - - -</p> <p>20 ... ANNE M. WEBER, M.D., after having</p> <p>21 been first duly sworn, was examined and</p> <p>22 testified as follows:</p> <p>23 - - -</p> <p>24 <b>DIRECT EXAMINATION</b></p> <p>25 - - -</p>	<p>- ANNE M. WEBER - DIRECT - Page 20</p> <p>1 vaginally, in the treatment of women with prolapse.</p> <p>2 <b>Q. And they were evaluating how the mesh reacted</b></p> <p>3 <b>in the body?</b></p> <p>4 A. Yes.</p> <p>5 <b>Q. Just one thing, you don't have to lean down to</b></p> <p>6 <b>the mic.</b></p> <p>7 A. Okay.</p> <p>8 <b>Q. I don't want to make you uncomfortable.</b></p> <p>9 <b>Okay, Doctor. Now, who are the</b></p> <p>10 <b>investigators? Who were listed as the investigators</b></p> <p>11 <b>for the study or the ones that authored this</b></p> <p>12 <b>abstract?</b></p> <p>13 A. The authors of this abstract are Dr. Lucente,</p> <p>14 Dr. Hale, Dr. Miller -- those are urogynecologists</p> <p>15 who are paid consultants of Ethicon -- and</p> <p>16 Dr. Madigan who is an Ethicon employee.</p> <p>17 <b>Q. Now, did you have an opportunity to review data</b></p> <p>18 <b>with regard to this study?</b></p> <p>19 A. Yes, I did.</p> <p>20 <b>Q. And what did you do in order to evaluate what</b></p> <p>21 <b>was found by the study? Tell the jury what you did.</b></p> <p>22 A. I reviewed the Case Report Forms, which is a</p> <p>23 term that's used in research to describe what we</p> <p>24 call the raw data. So before it gets collected all</p> <p>25 together and the analysis begins, where -- whoever</p>

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<p>- ANNE M. WEBER - DIRECT - Page 21</p> <p>1 is recording the data is actually putting down the 2 information about that patient on paper. 3 <b>Q. And tell us a little more about a Case Report</b> 4 <b>Form. What's the purpose and how are they</b> 5 <b>constructed? And you can talk about the ones in</b> 6 <b>this study specifically.</b> 7 A. Yes. 8 So the Case Report Forms include the 9 information that's intended to be collected in the 10 course of the study. The patient is assigned a 11 number so that it doesn't -- her name isn't on the 12 paper so this is, for the purposes of the patient, 13 is important for confidentiality. And then there's 14 a set of documents that are the beginning and then 15 different points in time as she goes through 16 follow-up. And this is to record what's been 17 specified in the protocol as to the important points 18 to consider. 19 And something that's important to 20 remember is that if it's not in the protocol and 21 it's not on the Case Report Form, if it's not 22 specifically asked for, you can easily realize it's 23 not going to be captured. That piece of information 24 won't get captured. 25 <b>Q. Was there any type of medical issue that was</b></p>	<p>- ANNE M. WEBER - DIRECT - Page 23</p> <p>1 So the study abstract reports certain 2 results, including the mesh exposure which has also 3 been termed mesh erosion, the prolapse recurrence 4 rate, meaning does the prolapse come back. And 5 Ethicon, in the context of this abstract, reported 6 certain rates. As you can see, 9.4 percent of women 7 who experienced a mesh exposure by one year and 8 24 percent of women who experienced a prolapse 9 recurrence by one year. 10 <b>Q. How many patients were studied?</b> 11 A. All together, 169 patients were entered into 12 the study. A smaller number of those women reached 13 one year of follow-up, and that's represented in the 14 129 patients there. 15 <b>Q. Now, so you have the Ethicon rate, those are</b> 16 <b>the rates that are in this abstract that was</b> 17 <b>reported?</b> 18 A. Yes. 19 <b>Q. What is the column "actual corrected"? What</b> 20 <b>does that mean?</b> 21 A. So that represents what I calculated based on 22 my independent review of the Case Report Forms 23 themselves. 24 <b>Q. Now, the way that you reviewed these Case</b> 25 <b>Report Forms -- first of all, what kind of a volume</b></p>
<p>- ANNE M. WEBER - DIRECT - Page 22</p> <p>1 <b>not listed on the Case Report Forms that was</b> 2 <b>significant to you?</b> 3 A. Yes. 4 <b>Q. Tell the jury what wasn't asked for on those</b> 5 <b>forms.</b> 6 A. The Case Report Forms didn't have any 7 recording -- any spot to record specifically the 8 recurrence of mesh contraction or retraction, which 9 is a very important complication that occurs with 10 Gynemesh PS mesh. 11 <b>Q. Okay. Now, this abstract, this was presented</b> 12 <b>someplace to other doctors?</b> 13 A. Yes. 14 <b>Q. And there's data on it and results listed,</b> 15 <b>right?</b> 16 A. Yes. 17 <b>Q. Okay. Let's put up the PowerPoint slide of the</b> 18 <b>Gynemesh PS study, please.</b> 19 (Technician complied.) 20 (Document displayed.) 21 <b>BY MR. SLATER:</b> 22 <b>Q. Okay. Doctor, please walk the jury through</b> 23 <b>what this slide that was prepared -- what that</b> 24 <b>shows; what that tells the jury.</b> 25 A. Yes.</p>	<p>- ANNE M. WEBER - DIRECT - Page 24</p> <p>1 <b>of paper are we talking about?</b> 2 A. Well, for each patient, 169 to start, 129 to 3 follow, there would be about 30 pages for each 4 patient. 5 <b>Q. And you reviewed that your own -- on your own,</b> 6 <b>yourself?</b> 7 A. Yes, I did. 8 <b>Q. When you reviewed this data, did you review</b> 9 <b>this data differently than you would have if you</b> 10 <b>were involved in a clinical study that you were</b> 11 <b>seeking to present at a national meeting or to</b> 12 <b>ultimately publish -- the types of things you've</b> 13 <b>done in your career?</b> 14 A. No, it was exactly the same. 15 <b>Q. And tell the jury your findings when you</b> 16 <b>reviewed the data on your own.</b> 17 A. So what I found in terms of mesh exposure was 18 that it had actually occurred to 24 women, which 19 represents 15.4 percent. And for the prolapse 20 recurrence, that it had happened to 47 women with a 21 slightly larger denominator, as you can see there, 22 139, which represents almost 34 percent. So that's 23 quite a bit deal higher than what had been reported 24 in the abstract. 25 <b>Q. Now, you have something about the data</b></p>

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<p>- ANNE M. WEBER - DIRECT - Page 25</p> <p>1 collection forms. You touched on this. Just please 2 explain what that means, that note right there. 3 A. Yes. 4 So just like we were just talking 5 about a minute ago, if it's not on the form, it's 6 not going to be collected. So on these data 7 collection forms, there were no specific areas to 8 record mesh contraction and retraction that we 9 talked about, dyspareunia, which is pain with sex, 10 pelvic pain or vaginal pain. And then just below 11 that you see the protocol had originally intended to 12 record the presence of granulation tissue, which is 13 reddish, nonhealing tissue that can happen in the 14 vagina that is often a precursor, what happens 15 before you actually see a mesh erosion develop. And 16 that was in the protocol intended to be collected. 17 But at some point in the future of the protocol it 18 was decided that there was no need to collect that 19 information. 20 Q. And what's your opinion on that? 21 A. My opinion is that that was important. It 22 needed to be collected. 23 Q. Why? 24 A. Well, as I said, if it's a precursor to mesh 25 erosion commonly, it's something the woman is</p>	<p>- ANNE M. WEBER - DIRECT - Page 27</p> <p>1 this slide which was used by defense counsel in 2 their opening statement? 3 A. Yes, I have. 4 Q. Do you have an opinion as to whether or not 5 it's accurate to say that Gynemesh PS shows 80 to 6 90 percent success? 7 A. Yes, I have an opinion. 8 Q. And what's your opinion? 9 A. My opinion is that is not accurate. 10 Q. And is that for the reasons you've just 11 explained? 12 A. Yes. 13 MR. SLATER: Okay. Take that down. 14 (Technician complies.) 15 BY MR. SLATER: 16 Q. Doctor, we've heard about the TVM study. Just 17 tell the jury in general what it was, just so we 18 have a record and a foundation. You know what it 19 is. Briefly tell the jury, what was the TVM study? 20 And we'll talk about that in a little bit. 21 A. The TVM study was a set of clinical studies 22 performed in France with the original TVM group and 23 also in the United States by Ethicon-paid 24 investigators to look at the early clinical results 25 of a prototype, not exactly the Prolift, but a</p>
<p>- ANNE M. WEBER - DIRECT - Page 26</p> <p>1 experiencing, symptoms are common. She can have 2 vaginal bleeding, vaginal discharge, pain with sex. 3 It's an important clinical event. 4 Q. Now, these data results, do you have an opinion 5 as to whether or not they represent an acceptable 6 risk-benefit profile for a procedure to treat 7 prolapse? 8 A. Yes, I have an opinion. 9 Q. And what is your opinion? 10 A. My opinion is that it is absolutely 11 unacceptable as a risk-benefit profile. 12 Q. Why is that? 13 A. Because you can see the recurrence rate is so 14 high. When you're thinking about whether you want 15 to do something, you think about the risks and 16 benefits. So the benefit proposed of using mesh in 17 the first place was it was going to repair the 18 prolapse so much better. That's clearly not true. 19 In addition to not repairing the 20 prolapse so much better, women are encumbered with 21 this incredibly high rate of complications; and this 22 is only one of them, the mesh erosion. 23 Q. Let's go to the next slide, which was the 24 PowerPoint slide from opening. 25 Doctor, have you had a chance to see</p>	<p>- ANNE M. WEBER - DIRECT - Page 28</p> <p>1 prototype of what would become the Prolift. 2 Q. Now, let's put up Exhibit -- hand it to counsel 3 first before you put it up, actually. 4 (Exhibit P-1752 marked for 5 identification.) 6 BY MR. SLATER: 7 Q. Dr. Weber, I'm going to ask you some questions 8 about the next exhibit, 1752. 9 A. Yes. 10 Q. Okay. Let's put that up. 11 (Document displayed.) 12 MS. ROBINSON: Objection. 13 THE COURT: Don't put it up. 14 Yes. What's the legal basis? 15 MS. ROBINSON: Cumulative for the -- 16 THE COURT: Oh, go ahead. I'm sorry. 17 Cumulative. 18 MS. ROBINSON: Cumulative for the 19 first portion of the slide. The information has 20 been elicited by Dr. Elliott. 21 THE COURT: Got it. Overruled. 22 MR. SLATER: Thank you. 23 (Document displayed.) 24 BY MR. SLATER: 25 Q. Doctor, Exhibit P-1752 titled French TVM Study,</p>



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<p>- ANNE M. WEBER - DIRECT - Page 29</p> <p>1 <b>Primary Endpoint, what is this exhibit?</b></p> <p>2 A. So this represents some data from the French</p> <p>3 side of the TVM study, the nine surgeon</p> <p>4 investigators who were paid by Ethicon to perform</p> <p>5 this study, like I said, on the TVM procedure, the</p> <p>6 Prolift prototype. And this represents some of</p> <p>7 their data on the recurrence rate.</p> <p>8 <b>Q. Now, there's two sections. First it says upper</b></p> <p>9 <b>limit of 90 percent confidence interval. And we've</b></p> <p>10 <b>heard about confidence intervals. You understand</b></p> <p>11 <b>what's been testified to?</b></p> <p>12 A. Yes.</p> <p>13 <b>Q. Okay. Just very simply, why is a confidence</b></p> <p>14 <b>interval used?</b></p> <p>15 A. A confidence interval is used in statistics and</p> <p>16 research to provide a range over what could be</p> <p>17 expected. If you did the study on a hundred</p> <p>18 different women and a hundred different women and a</p> <p>19 hundred different women, the average might be</p> <p>20 slightly different but the range would be -- they</p> <p>21 would fall within this expected range to a certain</p> <p>22 degree of confidence, and that's why we use these</p> <p>23 numbers.</p> <p>24 The 90 percent confidence interval,</p> <p>25 so there would still be 10 percent of -- you know,</p>	<p>- ANNE M. WEBER - DIRECT - Page 31</p> <p>1 which is less strict.</p> <p>2 <b>THE COURT:</b> What does "two sided"</p> <p>3 mean?</p> <p>4 <b>THE WITNESS:</b> Two sided means that --</p> <p>5 you imagine a bell curve, right. So two sided</p> <p>6 means both sides are being considered; that it's</p> <p>7 a possibility that things can turn out better on</p> <p>8 this side -- I'm sorry. Well, whichever way you</p> <p>9 look at it. There's a lower range, things might</p> <p>10 actually turn out better, and then there's a</p> <p>11 higher range, which means things might actually</p> <p>12 turn out worse.</p> <p>13 So what's typically done in research</p> <p>14 is a two-sided 95 percent confidence interval</p> <p>15 because that's why we're doing the research in</p> <p>16 the first place. Is it better or is it worse?</p> <p>17 Because if we knew the answer, we wouldn't have</p> <p>18 to do the research.</p> <p>19 So when they changed the protocol,</p> <p>20 they only looked at one side, the 90 percent,</p> <p>21 which, again, is a less strict form of looking</p> <p>22 at the data.</p> <p>23 <b>BY MR. SLATER:</b></p> <p>24 <b>Q. Okay. Now, what I'd like to do is -- and, Your</b></p> <p>25 <b>Honor, just to save time, can I approach and just</b></p>
<p>- ANNE M. WEBER - DIRECT - Page 30</p> <p>1 10 percent of the studies you did on hundreds of</p> <p>2 different women might fall outside this range, but</p> <p>3 at least 90 percent of them would fall within.</p> <p>4 <b>Q. And when that statistical analysis was done,</b></p> <p>5 <b>are those the rates that Ethicon itself found on</b></p> <p>6 <b>that standard?</b></p> <p>7 A. Yes.</p> <p>8 <b>Q. You're familiar with what the primary endpoint</b></p> <p>9 <b>was listed, 20 percent or greater?</b></p> <p>10 A. Yes.</p> <p>11 <b>Q. Did this meet the primary endpoint of the</b></p> <p>12 <b>study?</b></p> <p>13 A. This indicated a failure of the primary</p> <p>14 endpoint.</p> <p>15 <b>Q. Is that both at six months and one year?</b></p> <p>16 A. Yes.</p> <p>17 <b>Q. You have another section there, upper limit of</b></p> <p>18 <b>95 percent confidence interval, two sided. Why did</b></p> <p>19 <b>you put that there?</b></p> <p>20 A. That was what was in the original protocol to</p> <p>21 use this form of the statistic, and then Ethicon</p> <p>22 changed the protocol to a less strict definition.</p> <p>23 They went down from the 95 percent confidence</p> <p>24 interval, which is typically used in medical</p> <p>25 research, to the 90 percent confidence interval</p>	<p>- ANNE M. WEBER - DIRECT - Page 32</p> <p>1 <b>find an exhibit for Dr. Weber in that stack?</b></p> <p>2 <b>THE COURT:</b> Charles will find it.</p> <p>3 <b>MR. SLATER:</b> It's one that was used</p> <p>4 yesterday, the TVM study.</p> <p>5 <b>THE COURT:</b> Or we can pass them all</p> <p>6 down to you and you can find it.</p> <p>7 <b>MR. SLATER:</b> Awesome. Thanks,</p> <p>8 Charles.</p> <p>9 The next one is the French TVM study.</p> <p>10 I assume you guys still have it.</p> <p>11 (Pause.)</p> <p>12 <b>BY MR. SLATER:</b></p> <p>13 <b>Q. Okay. Doctor, what I've handed you is Exhibit</b></p> <p>14 <b>P-49. You're familiar with this document?</b></p> <p>15 A. Yes, I am.</p> <p>16 <b>Q. And have you relied on this?</b></p> <p>17 A. Yes.</p> <p>18 <b>Q. What is it?</b></p> <p>19 A. This is the study report that was generated by</p> <p>20 Ethicon to represent the data analysis up to and</p> <p>21 including the 12-month data from the French TVM</p> <p>22 study.</p> <p>23 <b>Q. Okay. On Page 3 there's a discussion of</b></p> <p>24 <b>inclusion criteria. Can you explain to the jury</b></p> <p>25 <b>what that means?</b></p>



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<p>- ANNE M. WEBER - DIRECT - Page 33</p> <p>1 A. Right. So when you design a study, you want to 2 set out at the very beginning to decide who you're 3 going to study. Obviously, you're not going to just 4 take all comers. You want women to be reasonably 5 similar in their problem so that when you apply the 6 treatment, you have some reliability in your 7 results. So the protocol was written to include 8 only women with advanced stage prolapse, so Stage 9 III and IV prolapse, that was symptomatic.</p> <p>10 <b>Q. On Page 40 there's a discussion of protocol</b> 11 <b>deviations. Can you explain to the jury what that</b> 12 <b>means?</b></p> <p>13 A. Right. So protocol deviations are when the 14 protocol isn't followed. Somebody made a mistake. 15 Something happened that wasn't according to the 16 protocol. And so in research terms that's called a 17 "protocol deviation."</p> <p>18 <b>Q. With regard to the inclusion criteria, is there</b> 19 <b>a discussion here of any deviations?</b></p> <p>20 A. Yes.</p> <p>21 <b>Q. Can you explain to the jury what the study</b> 22 <b>report states?</b></p> <p>23 A. There was a protocol deviation in that a 24 substantial number of women with Stage II prolapse, 25 which is a relatively early stage prolapse, were</p>	<p>- ANNE M. WEBER - DIRECT - Page 35</p> <p>1 <b>explanation of what that means. What's done -- are</b> 2 <b>you familiar with that?</b></p> <p>3 A. Yes.</p> <p>4 <b>Q. Did you use it in your practice?</b></p> <p>5 A. Yes.</p> <p>6 <b>Q. Did you use it in your research and your</b> 7 <b>papers?</b></p> <p>8 A. Yes.</p> <p>9 <b>Q. Please explain to the jury, we've heard it a</b> 10 <b>few times. Let's get an understanding of what it</b> 11 <b>means.</b></p> <p>12 A. Okay. So the system involves identifying 13 several points in the vagina and then their 14 relationship to the vaginal hymen, which is close to 15 the vaginal opening. So there are measures that are 16 inside the vagina which have a negative number, so 17 they're above zero. And then when the prolapse 18 actually extends outside the hymen, then the numbers 19 have a positive value.</p> <p>20 <b>Q. Doctor, let me stop you. When you're talking</b> 21 <b>about measuring, what's actually happening when a</b> 22 <b>doctor has a patient and is actually measuring? How</b> 23 <b>is that done?</b></p> <p>24 A. So it's like in the context of a pelvic exam 25 where the woman is lying on the examining table and</p>
<p>- ANNE M. WEBER - DIRECT - Page 34</p> <p>1 included in the study, and that was 16.4 percent, 2 which I said is a substantial number.</p> <p>3 <b>Q. Why, if at all, is that significant here?</b></p> <p>4 A. We know from other literature that women with 5 early stage prolapse have better results when 6 they're surgically treated. And that makes sense 7 intuitively; that if you're at an earlier stage, 8 things can be caught and the surgery works better. 9 And with Stage III and IV, women have outcomes that 10 are not as good. So by including women who had this 11 earlier form of prolapse, they're actually steering 12 the results to overall look more positive.</p> <p>13 <b>Q. Now, in terms of the overall data that was</b> 14 <b>returned here, do you have an opinion as to whether</b> 15 <b>that was significant?</b></p> <p>16 A. Yes.</p> <p>17 <b>Q. And is that for the reason you just explained?</b></p> <p>18 A. Yes.</p> <p>19 <b>Q. Now, how did they measure prolapse and whether</b> 20 <b>there was a prolapse recurrence per the study</b> 21 <b>protocol? What was the method they used?</b></p> <p>22 A. The prolapse was measured using a system called 23 POP-Q. POP is for pelvic organ prolapse, and Q is 24 for quantification.</p> <p>25 <b>Q. And if you could, just give the jury a little</b></p>	<p>- ANNE M. WEBER - DIRECT - Page 36</p> <p>1 her feet or her knees are up in stirrups, so the 2 doctor is viewing the vagina. The woman is asked to 3 bear down like as if she were having a bowel 4 movement -- that's called the Valsalva -- to make 5 the prolapse look at its most major extent. And 6 then just using a sterile little ruler measuring 7 those points on the vagina and their relation to the 8 hymen, whether they're still inside the vagina or 9 whether they've actually protruded outside of the 10 vagina.</p> <p>11 <b>Q. Okay. Were there any issues with POP-Q</b> 12 <b>measurements in this study?</b></p> <p>13 A. Yes.</p> <p>14 <b>Q. Can you tell the jury about that?</b></p> <p>15 A. Yes.</p> <p>16 As I reviewed the data, and, again, I 17 went through all the individual Case Report Forms 18 myself for this data, and there were a very high 19 number of errors in recording the POP-Q 20 measurements. And that, you know, I know we're all 21 human and nothing is ever perfectly 100 percent 22 done. But the level of errors that I found, which 23 is over 10 percent, really reflected, first of all, 24 an error rate that would never be accepted in a 25 study that was rigorously done.</p>

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<p>- ANNE M. WEBER - DIRECT - Page 37</p> <p>1 And the other thing is that it</p> <p>2 suggested that the investigators who were performing</p> <p>3 these measurements really had a fundamental</p> <p>4 misunderstanding of the proper way to do these</p> <p>5 measurements, and this is what was the primary</p> <p>6 outcome.</p> <p>7 <b>Q. And how does that impact, in your opinion, on</b></p> <p>8 <b>the reliability of the study?</b></p> <p>9 A. I think since the primary outcome depends on</p> <p>10 these measurements, then it's unreliable.</p> <p>11 <b>Q. Now, in looking at the actual data, you've</b></p> <p>12 <b>seen -- you've told us about the protocol deviations</b></p> <p>13 <b>with the women allowed 16 percent with Stage II.</b></p> <p>14 <b>You've told us about the POP-Q measurements. Even</b></p> <p>15 <b>with those issues, were the rates of recurrence</b></p> <p>16 <b>acceptable to you?</b></p> <p>17 A. No, they weren't.</p> <p>18 <b>Q. And this study, there were endpoints of -- one</b></p> <p>19 <b>year was the study, right?</b></p> <p>20 A. One year was the primary endpoint, yes.</p> <p>21 <b>Q. And they did some analyses at six months?</b></p> <p>22 A. Yes.</p> <p>23 <b>Q. Is that, in the world of clinical research,</b></p> <p>24 <b>considered long term, short term? What is it</b></p> <p>25 <b>considered?</b></p>	<p>- ANNE M. WEBER - DIRECT - Page 39</p> <p>1 of the Case Report Forms.</p> <p>2 At six months, Ethicon reported a</p> <p>3 mesh exposure rate of 14.9 percent, and at that time</p> <p>4 the Case Report Forms showed 17.2 percent. At one</p> <p>5 year, Ethicon reported the rate actually dropped to</p> <p>6 9.2 percent.</p> <p>7 <b>Q. How can the mesh exposure rate drop?</b></p> <p>8 A. The way that happened is because Ethicon</p> <p>9 decided that a woman had -- if she had a mesh</p> <p>10 exposure and it was treated and went away by the</p> <p>11 one-year visit, it would not be counted as if it</p> <p>12 didn't happen.</p> <p>13 <b>Q. I think you misspoke. You had a double</b></p> <p>14 <b>negative there.</b></p> <p>15 A. Oh, I'm sorry.</p> <p>16 <b>Q. Say it again.</b></p> <p>17 A. As if it didn't -- they -- they decided not to</p> <p>18 count mesh exposures that had occurred earlier</p> <p>19 before one year if the woman had been treated and</p> <p>20 the mesh exposure had gone away, so it was as if it</p> <p>21 didn't happen.</p> <p>22 <b>Q. Do you have an opinion, with your experience in</b></p> <p>23 <b>the clinical research field, as to whether that was</b></p> <p>24 <b>acceptable in this type of study?</b></p> <p>25 A. That was completely unacceptable. I have never</p>
<p>- ANNE M. WEBER - DIRECT - Page 38</p> <p>1 A. That's extremely short term for an implant</p> <p>2 that's expected to be in the woman's body for the</p> <p>3 rest of her life.</p> <p>4 <b>Q. Okay.</b></p> <p>5 <b>THE COURT:</b> Are you talking about</p> <p>6 both are short term, six months and one year?</p> <p>7 <b>THE WITNESS:</b> Yes. Both of those</p> <p>8 would be considered short term.</p> <p>9 <b>THE COURT:</b> Okay.</p> <p>10 <b>MR. SLATER:</b> Now, the next exhibit is</p> <p>11 going to be 1754.</p> <p>12 (Exhibit P-1754 marked for</p> <p>13 identification.)</p> <p>14 <b>MR. SLATER:</b> Okay. Let's put 1754</p> <p>15 up.</p> <p>16 (Document displayed.)</p> <p>17 <b>BY MR. SLATER:</b></p> <p>18 <b>Q. Doctor, we've put up Exhibit P-1754. It's</b></p> <p>19 <b>titled, French TVM Study Mesh Exposure Rates.</b></p> <p>20 <b>Please tell us what information is on that chart.</b></p> <p>21 A. Okay. So as I mentioned, I had reviewed all of</p> <p>22 the Case Report Forms myself, similar to what I did</p> <p>23 with the Gynemesh PS mesh study, and I found that</p> <p>24 there were substantial discrepancies between what</p> <p>25 Ethicon had reported and what I found by my review</p>	<p>- ANNE M. WEBER - DIRECT - Page 40</p> <p>1 seen anything in my long career of clinical research</p> <p>2 where this has been done.</p> <p>3 <b>Q. And just to make the record clear, what is mesh</b></p> <p>4 <b>exposure as you use that term here?</b></p> <p>5 A. Mesh exposure is what occurs when the mesh</p> <p>6 wears through or eats away at the vaginal wall. So</p> <p>7 instead of lying underneath the vaginal tissue, it</p> <p>8 actually comes to a position where it's literally</p> <p>9 exposed. So there's a raw open area in the vaginal</p> <p>10 wall where the mesh can be seen.</p> <p>11 <b>THE COURT:</b> Well, what would</p> <p>12 treatment be for that condition?</p> <p>13 <b>THE WITNESS:</b> Treatment typically</p> <p>14 starts out with medical treatment, estrogen in</p> <p>15 the vagina or antibiotics in the vagina. That</p> <p>16 only helps women between a third and a half of</p> <p>17 the time, and then surgical treatment is</p> <p>18 necessary. And even that is not universally</p> <p>19 successful and women sometimes need to go back</p> <p>20 for two or three or more reoperations in an</p> <p>21 attempt to correct this problem.</p> <p>22 <b>BY MR. SLATER:</b></p> <p>23 <b>Q. And when we talk about an operation, what is</b></p> <p>24 <b>actually happening? What has to be done by a</b></p> <p>25 <b>physician to remove the mesh when it's eroded</b></p>

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<p>- ANNE M. WEBER - DIRECT - Page 41</p> <p>1 through the vagina and it's now visible or can be 2 seen or felt?</p> <p>3 A. So what happens is that a new incision has to 4 be made in the vagina to bring the tissue from 5 around the edges of the erosion. The doctor snips 6 out the mesh that has been exposed, tries to remove 7 as much of the damaged or dead tissue as possible, 8 and then bring the edges of the healthy tissue back 9 together with stitches.</p> <p>10 Q. With regard to the 20.7 percent rate you found 11 at one year, did you have the opportunity to see 12 testimony from somebody in Ethicon with regard to 13 that rate?</p> <p>14 A. Yes.</p> <p>15 Q. And tell the jury what that was and if that was 16 significant to you.</p> <p>17 A. Yes. This was confirmed by one of the Medical 18 Affairs doctors in Ethicon as the correct rate.</p> <p>19 Q. That was Axel Arnaud?</p> <p>20 A. Yes.</p> <p>21 Q. Tell us the three-year rate information you 22 found. I don't think we went that far.</p> <p>23 A. Yeah. So at three years, now Ethicon is 24 reporting 14.4 percent. And what I found in the 25 Case Report Forms, that the correct rate was</p>	<p>- ANNE M. WEBER - DIRECT - Page 43</p> <p>1 the U.S. You told that to the jury?</p> <p>2 A. Yes.</p> <p>3 Q. And let's put up Exhibit P-1735. 4 (Document displayed.) 5 (Exhibit P-1735 marked for 6 identification.)</p> <p>7 BY MR. SLATER:</p> <p>8 Q. We have put up Exhibit 1735 titled U.S. TVM 9 Study, Primary Endpoint. Tell the jury what this 10 information is and why it's significant to you.</p> <p>11 A. Yes.</p> <p>12 So similar to the French TVM study, 13 this -- in the U.S. protocol they had the same 14 primary endpoint and the study was going to be 15 considered a failure if the occurrence -- recurrence 16 of prolapse exceeded 20 percent.</p> <p>17 So what Ethicon reported, again using 18 their 90 percent confidence interval, which is a 19 less strict way of reporting that, 19.6 percent, 20 only four-tenths lower, but they deemed this a 21 success. Except that the correct number is actually 22 22.4 percent.</p> <p>23 Q. How did that happen?</p> <p>24 A. That happened by me reviewing all the Case 25 Report Forms and seeing for myself exactly what had</p>
<p>- ANNE M. WEBER - DIRECT - Page 42</p> <p>1 23.5 percent. So almost one in four women had 2 experienced this complication.</p> <p>3 Q. Now, with regard to the findings that you've 4 told us about, based on your review of the actual 5 data, do you have an opinion as to whether or not 6 the French TVM study provided an acceptable 7 risk-benefit profile for a procedure like this?</p> <p>8 A. Yes, I have an opinion.</p> <p>9 Q. And what's your opinion for the jury?</p> <p>10 A. My opinion is that the risk-benefit profile was 11 completely unacceptable.</p> <p>12 Q. And just very briefly, just for the record, I 13 need you to explain why.</p> <p>14 A. Because of the very high rate of prolapse 15 recurrence within a short-term follow-up of only one 16 year, and we know already that prolapse recurrence 17 only gets more frequent as time goes on, and this 18 very high rate of complications which, again, 19 unfortunately, we know also continues to increase 20 with time because this is a permanent medical 21 implant that continues to be at risk for 22 complications for as long as the woman lives.</p> <p>23 Q. Okay. Now I want to turn to the U.S. TVM 24 study. So you had a bunch of doctors doing this in 25 France and then they had three doctors doing it in</p>	<p>- ANNE M. WEBER - DIRECT - Page 44</p> <p>1 been recorded on them.</p> <p>2 Q. And there were additional patients with 3 recurrences that hadn't been counted?</p> <p>4 A. Yes.</p> <p>5 Q. Under the 90 percent confidence interval, they 6 originally were going to use the more rigorous one. 7 Even under their reporting of the number of 8 recurrences, what was the rate they come up with?</p> <p>9 A. The rate was 21 percent.</p> <p>10 Q. Based on your evaluation of the data, does it 11 meet the primary endpoint?</p> <p>12 A. No. It's a failure.</p> <p>13 Q. By the way, were there POP-Q measurement 14 problems in this study also?</p> <p>15 A. Yes, there were.</p> <p>16 Q. Was there any particular investigator where 17 they were most prevalent?</p> <p>18 A. Yes. They were concentrated at the site of 19 Dr. Robinson, who became a Medical Affairs Director 20 at Ethicon.</p> <p>21 THE COURT: I'm not sure I heard it. 22 "Robbins"?</p> <p>23 THE WITNESS: Robinson.</p> <p>24 THE COURT: Robinson. Okay. 25 Proceed.</p>

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<p>- ANNE M. WEBER - DIRECT - Page 45</p> <p>1 BY MR. SLATER:</p> <p>2 Q. It's David Robinson?</p> <p>3 A. Yes.</p> <p>4 Q. So he was a doctor working as an investigator</p> <p>5 and then he later --</p> <p>6 MS. ROBINSON: Objection.</p> <p>7 THE COURT: Objection; leading?</p> <p>8 Sustained.</p> <p>9 BY MR. SLATER:</p> <p>10 Q. You mentioned that he later became a Medical</p> <p>11 Affairs Director?</p> <p>12 A. Yes.</p> <p>13 Q. Just explain what that means.</p> <p>14 A. Okay. So at this point he was a doctor in</p> <p>15 practice. He was involved in this investigation as</p> <p>16 paid by Ethicon, and then at some point in the near</p> <p>17 future, he was hired by Ethicon to become one of</p> <p>18 their Medical Affairs Directors.</p> <p>19 Q. Okay. Let's go now to -- they already have</p> <p>20 Exhibit 1737, right.</p> <p>21 Let's go to Exhibit 1737, please.</p> <p>22 This is 1737, titled U.S. TVM Study</p> <p>23 Mesh Exposure Rate. Please walk the jury through</p> <p>24 this.</p> <p>25 A. Yes. So now you're getting a little familiar</p>	<p>- ANNE M. WEBER - DIRECT - Page 47</p> <p>1 unacceptable.</p> <p>2 Q. Doctor, in front of you is an exhibit we've</p> <p>3 marked as PLT-0227.</p> <p>4 (Exhibit PLT-0227 marked for</p> <p>5 identification.)</p> <p>6 BY MR. SLATER:</p> <p>7 Q. Can you tell the jury what this document is?</p> <p>8 A. Yes. So this is a published medical article</p> <p>9 that represents the early results of a randomized</p> <p>10 trial -- remember we talked a little bit yesterday</p> <p>11 about randomized trial being the only kind of trial</p> <p>12 that you can assign cause and effect -- by</p> <p>13 Dr. Iglesia and her colleagues.</p> <p>14 Q. And let me stop you there.</p> <p>15 A. Okay.</p> <p>16 Q. Is there an article that in your opinion is</p> <p>17 medically reliable and authoritative?</p> <p>18 A. Yes.</p> <p>19 Q. Did you rely on this article?</p> <p>20 A. Yes.</p> <p>21 Q. Okay. The findings of this study, are they</p> <p>22 significant to you in connection with what we've</p> <p>23 just learned about the exposure rates from the</p> <p>24 Ethicon studies?</p> <p>25 A. Yes.</p>
<p>- ANNE M. WEBER - DIRECT - Page 46</p> <p>1 with this system. So in analyzing the Case Report</p> <p>2 Forms from the U.S. study, I calculated a correct</p> <p>3 rate of the mesh exposures. What Ethicon reported</p> <p>4 at six months was 9.5 percent. The correct rate is</p> <p>5 13.1 percent. At one year, again, the number</p> <p>6 actually dropped and was reported as 6 percent. The</p> <p>7 correct number is 15.7 percent.</p> <p>8 At three years, they didn't report it</p> <p>9 at all. There is no report of the three-year U.S.</p> <p>10 TVM data. The correct rate at that point was</p> <p>11 20.3 percent.</p> <p>12 At five years, they reported</p> <p>13 18.8 percent, and the correct rate was 27.1 percent.</p> <p>14 Q. These mesh exposure rates, do you have an</p> <p>15 opinion as to whether or not that's acceptable?</p> <p>16 A. Yes, I have an opinion.</p> <p>17 Q. What's your opinion?</p> <p>18 A. My opinion is this is absolutely unacceptable.</p> <p>19 Q. And why is that?</p> <p>20 A. That is because this is too high. In the</p> <p>21 literature, in Ethicon documents, referring back to</p> <p>22 previous studies where rates had been reported in</p> <p>23 the tens or the 15 percent range where they're</p> <p>24 identified as too high, this is too high. Now we're</p> <p>25 all the way up to 27 percent, and this is</p>	<p>- ANNE M. WEBER - DIRECT - Page 48</p> <p>1 Q. Tell the jury why.</p> <p>2 A. They're significant to me because the study</p> <p>3 designed a safety threshold in order to -- if they</p> <p>4 were seeing a particular complication, if it reached</p> <p>5 a certain point, they wanted to stop the study to</p> <p>6 avoid harming even more women. So this study</p> <p>7 protocol was designed with a safety threshold of</p> <p>8 15 percent mesh erosion.</p> <p>9 Q. What does that mean?</p> <p>10 A. That means if in the course of data collection</p> <p>11 and analysis they found that more than 15 percent of</p> <p>12 women had experienced a mesh erosion, they were</p> <p>13 going to stop enrolling patients into the study.</p> <p>14 Q. What does that mean, to stop enrolling them?</p> <p>15 A. That means you just keep -- you don't keep</p> <p>16 adding patients on. You stop doing that operation</p> <p>17 because you've decided it's not safe for women, but</p> <p>18 you keep following the women who've already had the</p> <p>19 operation so you can find out how they do in the</p> <p>20 longer term.</p> <p>21 Q. And what happened in this study?</p> <p>22 A. In this study they stopped enrolling women at</p> <p>23 three months when they realized that they had</p> <p>24 exceeded their safety threshold, 15.6 percent, and</p> <p>25 they stopped enrolling patients.</p>



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<p>- ANNE M. WEBER - DIRECT - Page 49</p> <p>1 <b>Q. Okay. The next exhibit, it should be 3196. Is</b>  2 <b>it up there?</b>  3 A. Yes.  4 <b>Q. Okay.</b>  5 <b>(Exhibit P-3196 marked for</b>  6 <b>identification.)</b>  7 <b>BY MR. SLATER:</b>  8 <b>Q. Doctor, Exhibit P-3196, are you familiar with</b>  9 <b>this document?</b>  10 A. Yes, I am.  11 <b>Q. And is it something you relied on?</b>  12 A. Yes.  13 <b>Q. What is this document?</b>  14 A. This is a research funding agreement between  15 Ethicon and Dr. Lucente.  16 <b>MR. SLATER:</b> Would you put that up,  17 please? Just the front cover. We're not going  18 to put anything else up.  19 <b>(Technician complies.)</b>  20 <b>BY MR. SLATER:</b>  21 <b>Q. Just to let the jury see what it looks like.</b>  22 <b>We could see the date there. Just</b>  23 <b>for the record, what was the date of this agreement?</b>  24 A. The date is October 30th, 2007.  25 <b>Q. Now, we know who Ethicon is, and just for the</b></p>	<p>- ANNE M. WEBER - DIRECT - Page 51</p> <p>1 A. Yes. So that began in 2005 and went up to  2 2008.  3 <b>Q. Okay. Now, let's put up the next PowerPoint,</b>  4 <b>the spreadsheet excerpt.</b>  5 <b>(Document displayed.)</b>  6 <b>What do we see here on this Lucente</b>  7 <b>IIS database slide? What's the jury seeing?</b>  8 A. So this is a little snapshot of what the  9 database looked like. If any of you are familiar  10 with Excel spreadsheets, that's what this was  11 entered on. So you have a column heading, the  12 patient number. And, again, for confidentiality  13 reasons, the patient name is never entered into data  14 like this, so she's assigned a number, her initial  15 visit, her height, her weight, et cetera, the data  16 collection for these women from their medical  17 charts.  18 <b>Q. Okay. Did you personally go through all the</b>  19 <b>database data, these pages and pages, and look at it</b>  20 <b>yourself, every patient?</b>  21 A. Yes, I did.  22 <b>Q. Okay. Let's go to the next PowerPoint slide,</b>  23 <b>the database, numbers of patients.</b>  24 <b>Doctor, what are we seeing here on</b>  25 <b>this slide, also entitled Lucente IIS Database?</b></p>
<p>- ANNE M. WEBER - DIRECT - Page 50</p> <p>1 <b>record, who is Vincent Lucente?</b>  2 A. Vincent Lucente is a gynecologist practicing in  3 Pennsylvania who has worked as an Ethicon consultant  4 for years and was their most important advocate in  5 promoting other surgeons using the Prolift procedure  6 across the country and across the world.  7 <b>Q. Now, if you could explain to the jury what</b>  8 <b>happened here. What is the investigator-initiated</b>  9 <b>study that was funded and performed pursuant to this</b>  10 <b>agreement? Take the jury through what this was.</b>  11 A. So Dr. Lucente submitted a proposal to Ethicon  12 to ask them for funding to perform an analysis and  13 upkeep of a database that he had regarding his  14 patients, he and the doctors in his practice, for  15 women who had undergone the Prolift procedure. So  16 he was asking for funding from Ethicon to keep this  17 database maintained and then to ultimately present  18 and publish the results of these data.  19 <b>Q. And just to orient the jury, we're talking</b>  20 <b>about patients that had Prolifts?</b>  21 A. Yes.  22 <b>Q. And what's the time frame?</b>  23 A. The time frame of when the patients had  24 undergone the Prolift?  25 <b>Q. Yes. Yes.</b></p>	<p>- ANNE M. WEBER - DIRECT - Page 52</p> <p>1 A. This is a summary of what the database  2 contained. So there were a total of 514 patients  3 entered into the database. And as I mentioned, they  4 spanned a time from August 2005 until July 2008.  5 There was a follow-up visit that occurred at four  6 months. Only 378 patients reached that four-month  7 visit and 136 were lost, which means they didn't  8 come back. And then at one year, only 134 patients  9 came back and 380 patients were lost to follow-up.  10 <b>Q. Okay. Now, Doctor, you have in front of you</b>  11 <b>the next exhibit, P-3215.</b>  12 A. Yes.  13 <b>Q. Doctor, what is Exhibit 3215?</b>  14 A. This is an e-mail that contains the content of  15 an abstract that was to be presented at a scientific  16 meeting.  17 <b>Q. And what was the scientific meeting? And when</b>  18 <b>are we talking about?</b>  19 A. This was to be presented at the 2009 meeting of  20 the International Urogynecology Association, which  21 is -- we abbreviate that IUGA.  22 <b>Q. Were you able to confirm that the text of the</b>  23 <b>abstract in this e-mail between the people at</b>  24 <b>Dr. Lucente's office was actually the same text in</b>  25 <b>the abstract presented?</b></p>



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<p>- ANNE M. WEBER - DIRECT - Page 53</p> <p>1 A. Yes; word for word.</p> <p>2 <b>Q. Okay. Now, you've gone through this and read</b></p> <p>3 <b>this?</b></p> <p>4 A. Yes, I have.</p> <p>5 <b>Q. And do you have an opinion as to whether or</b></p> <p>6 <b>not -- we'll go through the details of it -- as to</b></p> <p>7 <b>whether or not this abstract that presented data on</b></p> <p>8 <b>these Prolift patients, whether it accurately</b></p> <p>9 <b>reported that data?</b></p> <p>10 A. Yes, I have an opinion.</p> <p>11 <b>Q. What's your opinion?</b></p> <p>12 A. My opinion is that this does not accurately</p> <p>13 report the data in the database.</p> <p>14 <b>Q. Let's go to the next PowerPoint slide, "erosion</b></p> <p>15 <b>rate at one year."</b></p> <p>16 <b>Please tell the jury what we're</b></p> <p>17 <b>seeing here, Dr. Weber.</b></p> <p>18 A. What I found when I analyzed the database was</p> <p>19 that 10.6 percent of women experienced a mesh</p> <p>20 erosion at or before one year. What was reported in</p> <p>21 this abstract was that it was only 2.2 percent.</p> <p>22 <b>Q. And you had shown us on a prior slide -- I'm</b></p> <p>23 <b>not going to bring it up -- the number of women lost</b></p> <p>24 <b>to follow-up. What impact does that have, in your</b></p> <p>25 <b>opinion, in looking at this data and evaluating the</b></p>	<p>- ANNE M. WEBER - DIRECT - Page 55</p> <p>1 <b>I glazed over it. IIS, what does that mean?</b></p> <p>2 A. Investigator-initiated study.</p> <p>3 <b>Q. What does that mean here? What happened?</b></p> <p>4 A. So that means that Dr. Lucente went to Ethicon</p> <p>5 and proposed this study rather than the other way</p> <p>6 around. For example, the Gynemesh PS mesh studies</p> <p>7 and the TVM studies, Ethicon initiated that and</p> <p>8 signed up those doctors. In this case, Dr. Lucente</p> <p>9 went to Ethicon and requested this money.</p> <p>10 <b>Q. Okay. Please take us through the data on this</b></p> <p>11 <b>slide about the recurrence rates.</b></p> <p>12 A. Okay. Let's start at the bottom. The abstract</p> <p>13 reported that within one year, 13 percent of women</p> <p>14 had experienced a recurrence of their prolapse.</p> <p>15 What I found was at one year when you</p> <p>16 looked at women -- well, let me explain one thing.</p> <p>17 The treated compartment, so that means -- maybe</p> <p>18 you've heard some of this terminology. In speaking</p> <p>19 to each other as doctors, we divide the vagina up</p> <p>20 into compartments. So there's the anterior</p> <p>21 compartment, the apical compartment, the top of the</p> <p>22 uterus -- the top of the vagina that may have the</p> <p>23 cervix and uterus, and then the posterior</p> <p>24 compartment, the back wall.</p> <p>25 In this database, not everyone had</p>
<p>- ANNE M. WEBER - DIRECT - Page 54</p> <p>1 <b>safety profile we're seeing?</b></p> <p>2 A. It makes it extremely unreliable. What we know</p> <p>3 from other literature is that when women have a</p> <p>4 complication, they very frequently leave the</p> <p>5 original surgeon and seek care elsewhere. So that</p> <p>6 the fact that so many women did not follow up with</p> <p>7 Dr. Lucente and his partners suggests very strongly</p> <p>8 that a higher proportion of women actually</p> <p>9 experienced complications and simply did not report</p> <p>10 back to Dr. Lucente.</p> <p>11 <b>Q. This data difference, is that significant to</b></p> <p>12 <b>you?</b></p> <p>13 A. Yes.</p> <p>14 <b>Q. Why is that?</b></p> <p>15 A. That is because this abstract as presented to</p> <p>16 doctors in the scientific and clinical community see</p> <p>17 these numbers and they are probably reassured by</p> <p>18 this; that, oh, look, the erosion is only</p> <p>19 2.2 percent. It gives them a very misleading</p> <p>20 impression of what is actually going to happen to</p> <p>21 women.</p> <p>22 <b>Q. Let's go to the next slide, PowerPoint,</b></p> <p>23 <b>anatomic recurrence rate, one year.</b></p> <p>24 <b>Okay. Doctor, this slide, Lucente</b></p> <p>25 <b>IIS Database, I just want to say one thing. I think</b></p>	<p>- ANNE M. WEBER - DIRECT - Page 56</p> <p>1 Prolift that was total, meaning it was anterior and</p> <p>2 posterior. Some of them only had an anterior; some</p> <p>3 of them only had a posterior.</p> <p>4 So what I mean by the treated</p> <p>5 compartment means that aspect of the vagina that</p> <p>6 actually received the Prolift. So that they got an</p> <p>7 anterior Prolift, that was considered treated. And</p> <p>8 that rate was 32 percent.</p> <p>9 So almost a third of women at one</p> <p>10 year already had recurrence of prolapse where</p> <p>11 Prolift had been implanted.</p> <p>12 At the very top, when I considered</p> <p>13 all the compartments -- which is really what women</p> <p>14 care about. They care about whether their prolapse</p> <p>15 is gone and that no prolapse is ever going to come</p> <p>16 back -- it was practically half of women who had</p> <p>17 recurred by one year.</p> <p>18 <b>Q. 49.7 percent?</b></p> <p>19 A. Yes.</p> <p>20 <b>Q. And those figures, who calculated those</b></p> <p>21 <b>numbers?</b></p> <p>22 A. I did.</p> <p>23 <b>Q. And, again, just as you had testified earlier,</b></p> <p>24 <b>was there anything different you did in reviewing</b></p> <p>25 <b>this data than if you were doing it for a study in</b></p>

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1 the medical community?

2 A. No; exactly the same.

3 **Q. Before we go off this slide, did you have the**

4 **chance to read the deposition testimony of**

5 **Dr. Lucente and his partner, Dr. Murphy?**

6 A. Yes.

7 **Q. Did you learn anything from those depositions**

8 **of significance regarding how Dr. Lucente recorded**

9 **whether somebody had success or failure or whether**

10 **they re-prolapsed?**

11 A. Yes.

12 **Q. Please tell the jury what you learned from that**

13 **deposition testimony.**

14 A. Dr. Lucente had a habit of not recording a

15 complete POP-Q measurements. We talked about the

16 POP-Qs. There are five points that are particularly

17 important in determining whether a woman had

18 prolapse or not. And he testified that he felt he

19 could look at a woman without making measurements

20 and decide whether or not she had recurrent

21 prolapse.

22 **Q. Do you have an opinion as to whether that**

23 **raises any issues?**

24 A. Yes.

25 **Q. What is that?**

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1 A. It raises issues in the sense that that's

2 completely unacceptable as far as a research

3 practice, and also because we know Dr. Lucente has

4 an extremely high financial bias related to Ethicon

5 that he would be inclined to more favorably report

6 the outcomes.

7 **Q. Was Dr. Lucente involved in the Gynemesh PS**

8 **study and the TVM study you've already gone through**

9 **for the jury?**

10 A. Yes, he was.

11 **Q. What was his involvement?**

12 A. He was an investigator.

13 **Q. So his data would have been included in the**

14 **results?**

15 A. Yes.

16 **Q. In the abstract, at the bottom there's an**

17 **author's disclosure information. Is there anything**

18 **significant about what they disclosed there?**

19 A. Yes.

20 **Q. Please tell the jury what that is.**

21 A. They disclosed incorrectly that none of the

22 authors had any disclosures worth making, which

23 means -- disclosures mean do you have an association

24 with anyone like a company that could potentially

25 bias your results.

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1 **Q. What did they say here?**

2 A. They said they had no disclosures to make,

3 despite the fact that they are all paid Ethicon

4 consultants.

5 **THE COURT:** All Ethicon what?

6 **THE WITNESS:** Consultants.

7 **THE COURT:** "Consultants."

8 **BY MR. SLATER:**

9 **Q. Now, why is that an issue for people reading**

10 **the study and the data?**

11 A. It's been well established in the literature

12 that -- which is why these disclosures are made in

13 the first place -- that when investigators are

14 receiving money -- that's basically the definition

15 of a financial bias -- that they are inclined to

16 record things more favorably which includes more

17 favorably good outcomes and minimizing bad outcomes

18 or complications.

19 **Q. Based on your review of all the medical**

20 **literature and the documents in this case, did**

21 **Ethicon rely, to any extent, on Dr. Lucente's**

22 **literature and his reports of results with Prolift**

23 **patients?**

24 A. Yes, absolutely.

25 **Q. Did Dr. Lucente ever report complication or**

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1 **recurrence rates like what you found when you went**

2 **through his data yourself?**

3 A. No.

4 **Q. Can you characterize the difference?**

5 A. The difference is that he never reported

6 anything resembling this. And as you saw just by

7 this one example in this abstract, reporting results

8 that are far more favorable to the Prolift than what

9 actually occurred, even to the extent of reporting

10 in a series of 350 patients that no mesh exposures

11 had occurred at all.

12 Now, we know that it occurs in at

13 least 10 percent of women, at least. 350 patients,

14 no exposures. And in response to that, one of

15 Ethicon's medical directors replied: Who believes

16 Dr. Lucente's group --

17 **MS. ROBINSON:** Objection.

18 Nonresponsive. Move to strike.

19 **THE COURT:** Overruled.

20 Continue.

21 **THE WITNESS:** Who believes

22 Dr. Lucente's group when they report zero

23 erosions? Nobody.

24 **BY MR. SLATER:**

25 **Q. Now, based on your review of the Gynemesh PS**

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<p>- ANNE M. WEBER - DIRECT - Page 61</p> <p>1 study data, the TVM study data, and Dr. Lucente's</p> <p>2 IIS reported data, do you have an opinion as to</p> <p>3 whether or not all that data together presents an</p> <p>4 acceptable or an unacceptable risk-benefit profile</p> <p>5 for this procedure?</p> <p>6 A. Yes, I have an opinion.</p> <p>7 Q. Please tell the jury your opinion.</p> <p>8 A. I have the opinion that it is absolutely</p> <p>9 unacceptable in terms of a risk-benefit profile.</p> <p>10 Q. And just for the record, is that for the</p> <p>11 reasons you've explained with regard to the other</p> <p>12 studies as well?</p> <p>13 A. Yes.</p> <p>14 Q. Okay. Let's go to the next document. It's in</p> <p>15 front of you. And it's been -- we'll just put the</p> <p>16 front page up. It's Exhibit P-2137. This is the</p> <p>17 Clinical Expert Report signed January 14, 2005.</p> <p>18 A. Yes.</p> <p>19 Q. Are you familiar with this document?</p> <p>20 A. Yes.</p> <p>21 Q. Have you read it and reviewed all of the</p> <p>22 references and the information in it?</p> <p>23 A. Yes.</p> <p>24 (Exhibit P-2137 marked for</p> <p>25 identification.)</p>	<p>- ANNE M. WEBER - DIRECT - Page 63</p> <p>1 pelvic floor repair appears to be safe and</p> <p>2 effective -- efficacious.</p> <p>3 Q. You mentioned this before, but in this context,</p> <p>4 the Gynemesh PS study, did that serve as an adequate</p> <p>5 basis to evaluate mesh contraction?</p> <p>6 A. No.</p> <p>7 Q. Why not?</p> <p>8 A. Remember we talked, they didn't even have a</p> <p>9 space on the Case Report Form to record whether or</p> <p>10 not mesh contraction had occurred.</p> <p>11 Q. At this time in January of 2005, was there</p> <p>12 published literature by the TVM group regarding</p> <p>13 retraction?</p> <p>14 A. Yes.</p> <p>15 Q. And was that significant to you in this?</p> <p>16 A. Yes.</p> <p>17 Q. And what was the message of that published</p> <p>18 literature?</p> <p>19 A. The message was that the mesh contraction is a</p> <p>20 very worrying complication, impossible to predict in</p> <p>21 terms of in which women this is going to occur to a</p> <p>22 severe degree, and is something that needs to be</p> <p>23 further studied in order to reduce this occurrence</p> <p>24 to make this a safe product.</p> <p>25 Q. If the available clinical evidence and medical</p>
<p>- ANNE M. WEBER - DIRECT - Page 62</p> <p>1 BY MR. SLATER:</p> <p>2 Q. Doctor, having reviewed this, do you have an</p> <p>3 opinion as to whether or not this Clinical Expert</p> <p>4 Report is sufficient to establish that there was</p> <p>5 clinical evidence demonstrating the Prolift was safe</p> <p>6 and effective and could be marketed on a widespread</p> <p>7 basis as it was?</p> <p>8 A. Yes, I have an opinion.</p> <p>9 Q. Please tell the jury your opinion.</p> <p>10 A. My opinion is that this Clinical Expert Report</p> <p>11 does not contain sufficient information to conclude</p> <p>12 that the Prolift was safe and effective and should</p> <p>13 be marketed on a widespread basis.</p> <p>14 Q. Doctor, at the end of the report it talks about</p> <p>15 "contraction." And that's on the last page.</p> <p>16 A. Yes.</p> <p>17 Q. And what is ultimately the conclusion about</p> <p>18 contraction in this report?</p> <p>19 A. The conclusion is there were no instances of</p> <p>20 tissue contraction reported in the Gynecare Gynemesh</p> <p>21 clinical evaluation.</p> <p>22 Q. And what did that lead the -- how did that</p> <p>23 drive the conclusion in this report?</p> <p>24 A. That led to the conclusion that the use of the</p> <p>25 Prolift pelvic floor repair kits for the purpose of</p>	<p>- ANNE M. WEBER - DIRECT - Page 64</p> <p>1 literature had been evaluated in the way that you</p> <p>2 believe it should have been, what do you believe the</p> <p>3 appropriate conclusion would have been in this</p> <p>4 Clinical Expert Report?</p> <p>5 A. The appropriate conclusion should have been</p> <p>6 that Prolift was in no way safe and effective and</p> <p>7 should never have been marketed.</p> <p>8 Q. Okay.</p> <p>9 MR. SLATER: We can take that down.</p> <p>10 (Technician complies.)</p> <p>11 BY MR. SLATER:</p> <p>12 Q. Doctor, we have up here a PowerPoint slide used</p> <p>13 by the defense in opening statements. You've seen</p> <p>14 this?</p> <p>15 A. Yes.</p> <p>16 Q. I'd like to ask you about the Prolift, where</p> <p>17 they say a 16.7 percent of new onset dyspareunia.</p> <p>18 Do you have an opinion as to whether</p> <p>19 or not that is an accurate representation?</p> <p>20 A. Yes, I have an opinion.</p> <p>21 Q. What's your opinion?</p> <p>22 A. My opinion is that that is not accurate at all.</p> <p>23 Q. Why do you say that? What's the basis of that</p> <p>24 opinion?</p> <p>25 A. The basis of that opinion is my review of the</p>

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<p>- ANNE M. WEBER - DIRECT - Page 65</p> <p>1 article from which this was drawn and a careful 2 analysis of the information presented in that 3 article. 4 <b>Q. And take the jury through what, in your 5 opinion, the appropriate number should be here.</b> 6 A. The appropriate number of women with new onset 7 dyspareunia after the Prolift procedure was 8 39 percent. 9 <b>Q. And why do you say that?</b> 10 A. I say that because that's what was reported in 11 this article based on questionnaire results where 12 the women themselves were asked -- 13 <b>MS. ROBINSON:</b> Objection. 14 <b>THE COURT:</b> Legal basis? 15 <b>MS. ROBINSON:</b> May we approach? 16 <b>THE COURT:</b> Sure. 17 - - - 18 (The following discussion transpired 19 at sidebar out of the hearing of the jury:) 20 - - - 21 <b>THE COURT:</b> Legal basis for the 22 objection? 23 <b>MS. ROBINSON:</b> Your Honor -- 24 <b>THE COURT:</b> What is the legal basis 25 for the objection?</p>	<p>- ANNE M. WEBER - DIRECT - Page 67</p> <p>1 <b>COURT CRIER:</b> Please remain seated 2 until the jury has left the courtroom. 3 Jurors, please turn your clipboards, 4 and watch your step. 5 - - - 6 (Whereupon the jury exited the 7 courtroom at 11:04 a.m.) 8 - - - 9 (The following discussion transpired 10 in chambers, out of the hearing of the jury:) 11 <b>THE COURT:</b> Okay. This article was 12 not referenced in any of the 500-plus pages of 13 her disclosure; is that what you're telling me? 14 <b>MS. ROBINSON:</b> The article itself is. 15 But the fact that she's going to reanalyze the 16 data in that article was not. 17 <b>THE COURT:</b> Okay. Was defense ever 18 put on notice in any of the 5-, 6-, 700 pages 19 that this witness has disclosed in this total 20 litigation that some reanalysis of this article 21 was involved or was done? 22 <b>MR. SLATER:</b> A specific intent to 23 reanalyze the article was not discussed. What 24 she did in the report was she discussed a 25 massive amount of literature. She talked about</p>
<p>- ANNE M. WEBER - DIRECT - Page 66</p> <p>1 <b>MS. ROBINSON:</b> Your Honor, this 2 expert was never disclosed on the fact that she 3 was going to be assessing and evaluating the 4 Lowman article and offering an opinion that it 5 was improper. 6 <b>THE COURT:</b> The Lowman article is not 7 contained in all 500 pages? 8 <b>MR. SLATER:</b> It's clearly discussed 9 in the reports. 10 <b>THE COURT:</b> I'm sorry. 11 <b>MR. SLATER:</b> I'm sorry, Judge. 12 <b>THE COURT:</b> Do you want to talk? 13 <b>MR. SLATER:</b> I'm sorry, Judge. 14 <b>THE COURT:</b> Please talk to each 15 other. 16 (Whereupon an off-the-record 17 discussion was held.) 18 (Pause in the proceedings.) 19 <b>THE COURT:</b> We'll take a ten-minute 20 recess. 21 I'll see counsel in chambers. 22 (Sidebar discussion paused.) 23 (The following transpired in open 24 court in the presence of the jury:) 25 - - -</p>	<p>- ANNE M. WEBER - DIRECT - Page 68</p> <p>1 the fact that it does not represent an adequate 2 or acceptable risk-benefit profile. So they're 3 certainly on notice that with regard to any of 4 the articles in the report, she could take the 5 article and explain what it showed and why that 6 enters into her opinions. 7 <b>THE COURT:</b> Okay. But nowhere in all 8 the -- how many pages was disclosed in this 9 whole litigation from this witness? 10 <b>MR. SLATER:</b> I'd have to estimate, 11 probably 7- or 800 pages. 12 <b>THE COURT:</b> Okay. In none of the 800 13 pages did she disclose a reanalysis of the 14 Lowman article that she had done; is that 15 accurate? 16 <b>MR. SLATER:</b> Never in those terms. I 17 don't consider this a reanalysis, though, Judge. 18 I just consider it her telling what the data 19 shows. 20 <b>THE COURT:</b> Read back the question 21 that was objected to. 22 - - - 23 (Whereupon the court reporter read 24 back from the record as follows: 25 "Question: And why do you say that?</p>



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<p>- ANNE M. WEBER - DIRECT - Page 69</p> <p>1 "Question: And take the jury through 2 what, in your opinion, the appropriate number 3 should be here.") 4 - - - 5 (Whereupon an off-the-record 6 discussion was held.) 7 - - - 8 <b>THE COURT:</b> Wait. Let's do it 9 differently. 10 Put on the record the question you're 11 going to ask her about the Lowman -- first off, 12 tell me what the Lowman article is. 13 <b>MR. SLATER:</b> The defense expert -- 14 one of their two experts is someone named 15 Dr. Joye Lowman. When she was a Fellow, she 16 wrote an article, along with some other people, 17 where they stated in the article that the 18 dyspareunia rate was 16.7 percent. 19 <b>THE COURT:</b> Okay. 20 <b>MR. SLATER:</b> If you go through the 21 article and you just read the numbers of 22 patients and what they reported, you can add 23 them up for yourself and you'll come to 24 different numbers. And that's all she's doing. 25 And what happened was --</p>	<p>- ANNE M. WEBER - DIRECT - Page 71</p> <p>1 <b>THE COURT:</b> Okay. Got it. 2 Yes. Anything further? Is there 3 anything further? 4 <b>MS. ROBINSON:</b> No, Your Honor. 5 <b>THE COURT:</b> Okay. The objection is 6 overruled. 7 Let's take a break. 8 <b>MR. SLATER:</b> Yes, Your Honor. 9 <b>MR. MORIARTY:</b> Your Honor, you at one 10 point last week asked for the transcripts of the 11 videos that had been played. 12 <b>THE COURT:</b> Yeah. Do we have it? 13 <b>MR. MORIARTY:</b> Here. (Indicating.) 14 So sorry it took so long. There was 15 some technical difficulties getting the 16 bigger... 17 <b>THE COURT:</b> Fine. Thank you. 18 (Sidebar discussion concluded.) 19 - - - 20 (Whereupon a recess was taken.) 21 - - - 22 <b>COURT CRIER:</b> Please remain seated 23 until the jury reaches the jury box. 24 (Whereupon the jury entered the 25 courtroom at 11:13 a.m.)</p>
<p>- ANNE M. WEBER - DIRECT - Page 70</p> <p>1 <b>THE COURT:</b> Hold on. Wait a minute. 2 And when was this Lowman article 3 published, in relation to when the product went 4 on the market? 5 <b>MR. SLATER:</b> Around 2007, I think. 6 <b>THE COURT:</b> No. That doesn't help 7 me. 8 <b>MR. SLATER:</b> Oh. The product went on 9 the market in '05. 10 <b>THE COURT:</b> So like two years roughly 11 after it was on the market. 12 <b>MR. SLATER:</b> Right. 13 <b>THE COURT:</b> And is Lowman a witness 14 you're going to call? 15 <b>MS. ROBINSON:</b> She is, Your Honor. 16 <b>THE COURT:</b> Was Lowman referenced in 17 the 700 pages? 18 <b>MR. SLATER:</b> Definitely. The article 19 is referenced. And what we're responding to 20 now, frankly, is a slide that was put up in 21 front of the jury. And obviously I didn't know 22 they were going to put the slide up. And she's 23 just taking the jury through whether the slide 24 is accurate. And all she's doing is telling 25 what the numbers are per the article.</p>	<p>- ANNE M. WEBER - DIRECT - Page 72</p> <p>1 (The following transpired in open 2 court in the presence of the jury): 3 - - - 4 <b>COURT CRIER:</b> Court is back in 5 session. 6 <b>THE COURT:</b> Next question, please. 7 <b>BY MR. SLATER:</b> 8 <b>Q. Okay. Doctor, just briefly tell us why you</b> 9 <b>said 39 percent would be the appropriate rate there</b> 10 <b>based on the study that number came from.</b> 11 <b>A. Yes. When I examined the data reported in this</b> 12 <b>article, the questionnaire results showed that</b> 13 <b>39 percent of women experienced new dyspareunia,</b> 14 <b>pain with sex, after the Prolift insertion.</b> 15 <b>The 16.7 percent comes from a chart</b> 16 <b>review that the authors decided to do instead of</b> 17 <b>relying on the patient's questionnaires. So a chart</b> 18 <b>review, as you may know, is where they just look</b> 19 <b>back and see what the doctors have recorded. And</b> 20 <b>they chose to rely on the chart review rather than</b> 21 <b>on the questionnaires that the patients filled out</b> 22 <b>themselves.</b> 23 <b>Q. And in this context, what is your assessment of</b> 24 <b>that decision?</b> 25 <b>A. My assessment of that decision is that it</b></p>



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<p>- ANNE M. WEBER - DIRECT - Page 73</p> <p>1 minimized what the women were reporting regarding 2 their problems they were having with sex. 3 <b>Q. Okay. We could take that down.</b> 4 <b>The next, Doctor, in front of you is</b> 5 <b>an Exhibit PLT-0629.</b> 6 A. Okay. 7 <b>Q. And this is a -- well, what is this document?</b> 8 <b>Very simply, what is the document?</b> 9 A. This is an abstract from the TVM group 10 reporting on a group of patients who had undergone 11 the TVM procedure that was before the Ethicon-funded 12 studies of the TVM that we've already looked at this 13 morning. 14 <b>Q. Is this medically reliable and authoritative?</b> 15 A. Yes. 16 <b>Q. Is it something you relied on?</b> 17 A. Yes. 18 <b>Q. Okay. Let's go to the next exhibit, PLT-0089.</b> 19 <b>(Exhibit PLT-0089 marked for</b> 20 <b>identification.)</b> 21 <b>BY MR. SLATER:</b> 22 <b>Q. Very simply, what is this document?</b> 23 A. This is a published medical article from the 24 TVM group, the French doctors, who are again 25 reporting on a group of the patients who underwent</p>	<p>- ANNE M. WEBER - DIRECT - Page 75</p> <p>1 <b>Q. And the short follow-up of 3.6 months, why is</b> 2 <b>that significant here?</b> 3 A. It's significant because, as we know, the 4 experience of complications is only going to 5 increase as time goes by. 6 <b>Q. Okay. Let's go to the next one, P-1499.</b> 7 <b>(Exhibit P-1499 marked for</b> 8 <b>identification.)</b> 9 <b>BY MR. SLATER:</b> 10 <b>Q. Are you familiar with this document?</b> 11 A. Yes. 12 <b>Q. What is this?</b> 13 A. This is an abstract from the French TVM doctors 14 reporting their preliminary results of the Prolift 15 technique. 16 <b>Q. How many patients are they talking about here?</b> 17 A. 110 patients. 18 <b>Q. Is this medically reliable and authoritative?</b> 19 A. Yes. 20 <b>Q. Did you rely on this?</b> 21 A. Yes. 22 <b>Q. And it's very small type at the top left. This</b> 23 <b>was presented in Athens, Greece in September 2006?</b> 24 A. Yes. 25 <b>Q. Okay. What, if anything, is significant about</b></p>
<p>- ANNE M. WEBER - DIRECT - Page 74</p> <p>1 the TVM procedure before the Ethicon-funded TVM 2 studies. And in this study they were looking at 3 safety. 4 <b>Q. With regard to the -- well, first of all, is</b> 5 <b>this article medically reliable and authoritative?</b> 6 A. Yes. 7 <b>Q. Did you rely on it?</b> 8 A. Yes. 9 <b>Q. What information, if any, was significant to</b> 10 <b>you regarding complications and safety at the 3.6</b> 11 <b>months point this is looking at?</b> 12 A. What was significant to me, that at this 13 extremely short duration of follow-up of only about 14 three and a half months, they were reporting a high 15 frequency of complications. 16 <b>Q. And I think it might be in the abstract -- you</b> 17 <b>can find it -- what was the overall postsurgical</b> 18 <b>complication rate at 3.6 months?</b> 19 A. Okay. 33.6 percent. 20 <b>Q. Do you have an opinion as to whether that is</b> 21 <b>acceptable, concerning, anything like that?</b> 22 A. Yes. My opinion is that that's very 23 concerning, again, as I mentioned, at that very low 24 duration of follow-up and an extremely high rate of 25 complications.</p>	<p>- ANNE M. WEBER - DIRECT - Page 76</p> <p>1 <b>this presentation by the TVM group in</b> 2 <b>September 2006?</b> 3 A. It's significant to me that, again, in this 4 very short range of follow-up, they were reporting a 5 significant number of complications. And they found 6 that related to that, they needed to assess more 7 precisely functional and sexual outcomes before to 8 extend the indications of Prolift to young women or 9 to primary prolapse repair. 10 <b>Q. Let's just stop there. Let the siren go.</b> 11 A. Yes. 12 (Sirens outside courtroom.) 13 (Pause.) 14 <b>Q. Can you explain to the jury why that's</b> 15 <b>significant to you?</b> 16 A. Yes. 17 So these are the doctors who are 18 developing -- have been developing this technique; 19 and what they're seeing at this short duration of 20 follow-up is enough to concern them where they need 21 more information about the functional and sexual 22 outcomes of women before this product is introduced 23 in a widespread manner, and particularly for young 24 women, in part related to the sexual activity and in 25 part related to increasing the length of time that</p>

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<p>- ANNE M. WEBER - DIRECT - Page 77</p> <p>1 these women would carry the permanent implant and to</p> <p>2 primary prolapse repair, which means the first time</p> <p>3 the prolapse is fixed.</p> <p>4 <b>Q. And with regard to the Prolift and how the</b></p> <p>5 <b>Prolift was indicated and marketed, is there a</b></p> <p>6 <b>difference there?</b></p> <p>7 A. Yes.</p> <p>8 <b>Q. And what is that difference?</b></p> <p>9 A. The difference is that Prolift was marketed for</p> <p>10 almost all patients.</p> <p>11 <b>Q. Do you have an opinion as to whether that was</b></p> <p>12 <b>appropriate?</b></p> <p>13 A. Yes, I do.</p> <p>14 <b>Q. And what's your opinion?</b></p> <p>15 A. My opinion is that that was absolutely</p> <p>16 inappropriate.</p> <p>17 <b>Q. And I want to go to the next document and talk</b></p> <p>18 <b>a little more about this, P-2640.</b></p> <p>19 A. Yes.</p> <p>20 <b>Q. Is this a document you are familiar with and</b></p> <p>21 <b>relied on?</b></p> <p>22 A. Yes.</p> <p>23 <b>Q. What is this document?</b></p> <p>24 A. This document is a set of PowerPoint slides</p> <p>25 from a meeting of the TVM group that was held in</p>	<p>- ANNE M. WEBER - DIRECT - Page 79</p> <p>1 <b>Q. If it was going to be on the market, which we</b></p> <p>2 <b>know you've already given an opinion to the</b></p> <p>3 <b>contrary, but if it was going to be on the market,</b></p> <p>4 <b>how should it have been indicated?</b></p> <p>5 A. It should have been indicated for women who had</p> <p>6 no other options, who had advanced degree prolapse</p> <p>7 that was not able to be successfully treated with</p> <p>8 other types of surgery who had gone through other</p> <p>9 types of surgery and still had this recurrence.</p> <p>10 And, in fact, this is what professional</p> <p>11 organizations have belatedly come to realize as far</p> <p>12 as the very narrow indications that should exist for</p> <p>13 mesh use in prolapse surgery.</p> <p>14 <b>Q. Doctor, the next document, PLT-0489, are you</b></p> <p>15 <b>familiar with that document?</b></p> <p>16 A. Yes.</p> <p>17 <b>Q. Very briefly, what is this?</b></p> <p>18 A. This is a published medical article that</p> <p>19 studies women after they have had the Prolift placed</p> <p>20 and studies them by using an ultrasound to look at</p> <p>21 the permanent mesh implant.</p> <p>22 <b>Q. Is this article, in your opinion, medically</b></p> <p>23 <b>reliable and authoritative?</b></p> <p>24 A. Yes.</p> <p>25 <b>Q. Did you rely on it?</b></p>
<p>- ANNE M. WEBER - DIRECT - Page 78</p> <p>1 Paris on September 29, 2003.</p> <p>2 <b>Q. And if you turn within it, there's a page on</b></p> <p>3 <b>key subject requirements. Is there something of</b></p> <p>4 <b>significance there?</b></p> <p>5 A. Yes.</p> <p>6 <b>Q. What are they telling here about the</b></p> <p>7 <b>requirements for who they were saying should be in</b></p> <p>8 <b>the TVM study and operated on by this procedure?</b></p> <p>9 A. Most importantly, they required that women have</p> <p>10 Stage III or IV advanced prolapse, advanced stage</p> <p>11 prolapse, that was symptomatic.</p> <p>12 <b>Q. What does that mean?</b></p> <p>13 A. That means they were reserving the use of the</p> <p>14 Prolift or the TVM technique for women who had these</p> <p>15 advanced stages who were symptomatic, not for women</p> <p>16 with early stage prolapse.</p> <p>17 <b>Q. And, again, do you have an opinion as to</b></p> <p>18 <b>whether or not the indications for the Prolift were</b></p> <p>19 <b>appropriate or not, based on the literature you've</b></p> <p>20 <b>talked about here?</b></p> <p>21 A. Yes.</p> <p>22 <b>Q. What's that opinion?</b></p> <p>23 A. My opinion is that it was not appropriate in</p> <p>24 terms of extending or marketing the Prolift product</p> <p>25 to all -- almost all women.</p>	<p>- ANNE M. WEBER - DIRECT - Page 80</p> <p>1 A. Yes.</p> <p>2 <b>Q. And the authors of this, who were the people</b></p> <p>3 <b>who treated these patients?</b></p> <p>4 A. These are members of the French TVM group.</p> <p>5 <b>Q. The last name there, Jacquetin.</b></p> <p>6 A. Yes.</p> <p>7 <b>Q. That's Professor Jacquetin?</b></p> <p>8 A. Uh-huh.</p> <p>9 <b>Q. With regard to this study which studied with</b></p> <p>10 <b>ultrasounds what happened in the body, what is of</b></p> <p>11 <b>significance to you?</b></p> <p>12 A. What is of significance to me is the extremely</p> <p>13 high proportion of women who experienced mesh</p> <p>14 retraction that they could identify by ultrasound.</p> <p>15 <b>Q. And what were those figures?</b></p> <p>16 A. 89 percent of women who had anterior Prolift</p> <p>17 had moderate to severe retraction.</p> <p>18 <b>Q. Doctor, when they were measuring what</b></p> <p>19 <b>retraction is -- first of all, just to ground us,</b></p> <p>20 <b>what is retraction that you're discussing here?</b></p> <p>21 A. Retraction, mesh retraction or contraction --</p> <p>22 those terms are used interchangeably -- is when in</p> <p>23 the course of healing the tissue begins to shrink</p> <p>24 and the mesh is drawn along with it. So that</p> <p>25 instead of laying flat and occupying the space that</p>

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1 it was intended to occupy, it instead retracts  
2 literally. It becomes a smaller area. It becomes  
3 crunched up, bunched up. The mesh can become folded  
4 on itself. So that's what mesh retraction  
5 represents.  
6 **Q. You mentioned "bunching." How does bunching  
7 relate to retraction?**  
8 A. Yes. So you can just kind of imagine in your  
9 minds this what should be a flat piece of mesh. As  
10 it's undergoing the process of retraction, the  
11 substance of the mesh has to go somewhere, so it  
12 becomes wavy and folded and bunched so that it's --  
13 it's laying over itself. It's not a single flat  
14 layer.  
15 **Q. When the mesh originally goes into the body,  
16 does it go in flat?**  
17 A. No, it does not.  
18 **Q. And if they're bunching or uneven shaping to  
19 the mesh, what impact does that have on contraction?**  
20 A. That simply accelerates the process of  
21 contraction.  
22 **Q. Was Ethicon aware of this from the beginning?**  
23 A. Yes.  
24 **Q. Now, with regard to this study -- so what did  
25 they do? They did ultrasounds. And what did they**

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1 see?  
2 A. Yes, they did ultrasounds of the mesh implant.  
3 And what they found was exactly what we've been  
4 talking about. They could see the mesh folds. They  
5 could see what they described as an undulation, a  
6 waviness, a wavy appearance of the mesh, very  
7 dramatic thickening of the mesh instead of that  
8 thinness as it went in. Instead it was thickened,  
9 which represents not only the folding and the  
10 waviness, but also the scar tissue that builds up  
11 that occurs around the mesh itself.  
12 **Q. Is that known as scar plating or bridging  
13 fibrosis?**  
14 A. Yes.  
15 **Q. What's the clinical impact of that?**  
16 A. Very severe. This distorts the vagina. This  
17 causes pain. Remember that the anterior Prolift  
18 implant has those four arms that go out through the  
19 muscles and tissues of the groin. So that as the  
20 mesh, the body of the mesh implant is contracting,  
21 that's dragging on those mesh arms. They can't move  
22 because they're fixed in the tissue. So that  
23 contraction that's going on in the body of the mesh  
24 drags on those mesh arms, creates pain there in the  
25 muscles of the hip and thigh which just causes

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1 symptoms related to physical activity, obviously  
2 with vaginal anatomic distortion, but contraction  
3 also leads to a higher risk of erosions and  
4 recurrent prolapse. Women have, as you can easily  
5 imagine, terrific difficulties with sex, and that's  
6 the whole picture.  
7 **Q. Doctor, the next exhibit in front of you is  
8 P-1706.**  
9 A. Yes.  
10 **Q. Are you familiar with this document?**  
11 A. Yes.  
12 **Q. Did you rely on this?**  
13 A. Yes.  
14 **Q. Is it medically reliable and authoritative, in  
15 your opinion?**  
16 A. Yes.  
17 **Q. What is this document?**  
18 A. This represents a presentation, a slide set of  
19 presentations that were made at the International  
20 Urogynecology Association meeting.  
21 **Q. And it says June of 2009?**  
22 A. Yes.  
23 **Q. Is there a relationship between this document  
24 and the study you just told the jury about?**  
25 A. Yes.

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1 **Q. What is that relationship?**  
2 A. These are the same authors. These represent  
3 the same patients that we talked about in that  
4 ultrasound article.  
5 **Q. And what did they say in this presentation  
6 regarding the clinical impact of mesh shrinkage?  
7 There's a page -- about 14 pages in that I think  
8 discusses that.**  
9 **What of significance to you, most  
10 significant with regard to what you just told the  
11 jury about the mesh shrinkage?**  
12 A. They found that almost 20 percent of women,  
13 19.6 percent of women, had tenderness and pain on  
14 vaginal examination associated with the mesh  
15 shrinkage with an average pain score of 5 out of 10.  
16 **Q. Is that significant to you?**  
17 A. Yes.  
18 **Q. Why?**  
19 A. Because this is the clinical effect of the mesh  
20 contraction that we were just talking about a minute  
21 ago. You might be familiar with a pain scale where  
22 it starts at zero when you have no pain at all, and  
23 10 is the worst pain that you've ever experienced in  
24 your life. So this is an average of 5. Five is  
25 moderately severe pain. This is not mild, you know,

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1 something that you might be able to live with. This  
2 is a serious level of pain that's occurring in  
3 20 percent of these women. One in five of these  
4 women have this level of severity of pain.  
5 **Q. Doctor, with regard to all the literature and**  
6 **the studies and the medical issues you've discussed**  
7 **with the jury today, do you have an overall opinion**  
8 **about whether or not the risk-benefit profile for**  
9 **the Prolift was acceptable?**  
10 A. Yes, I do.  
11 **Q. What is your opinion?**  
12 A. My opinion is that the Prolift has a completely  
13 unacceptable risk-benefit profile.  
14 **Q. And is it for all the reasons you've explained**  
15 **to the jury today?**  
16 A. Yes.  
17 **Q. Let's go to the next exhibit, PLT-151.**  
18 **(Exhibit PLT-0151 marked for**  
19 **identification.)**  
20 **THE WITNESS:** I believe it's 0151.  
21 **MR. SLATER:** 0151.  
22 I might have given the extra copy.  
23 **BY MR. SLATER:**  
24 **Q. Doctor, is that an article you're familiar**  
25 **with?**

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1 A. Yes.  
2 **Q. Is it medically reliable and authoritative, in**  
3 **your opinion?**  
4 A. Yes.  
5 **Q. Have you relied on it?**  
6 A. Yes.  
7 **Q. Just tell the jury simply what it is.**  
8 A. So this is a published medical article that is  
9 called a systematic review. What these authors did  
10 is search through all of the medical literature for  
11 articles that were relevant to this topic. And this  
12 is complications and reoperation rates after vaginal  
13 surgical repair of prolapse. And so they took all  
14 the articles from the literature and combined the  
15 data to come up with an overall summary of what the  
16 literature shows.  
17 **Q. And what, if any, significance -- what was**  
18 **significant to you about that?**  
19 A. This was significant to me because in the way  
20 that they presented it, they divided the women up  
21 into three groups where the kind of surgery they  
22 underwent was either traditional suture procedures  
23 or an abdominal sacrocolpopexy, which is an  
24 abdominal way to fix prolapse, and mesh. Mesh kits,  
25 I should say.

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1 **Q. And what's the most important finding from your**  
2 **perspective?**  
3 A. The most important finding was that the  
4 complications and reoperation rate was highest in  
5 the group of women who had undergone the mesh kits,  
6 even though they had the shortest duration of  
7 follow-up. And as we've already talked about this  
8 morning, the longer you study women or the longer  
9 they go through their lives, they're going to -- the  
10 frequency of complications is only going to  
11 increase.  
12 So the fact that a duration of  
13 follow-up that was significantly shorter than for  
14 the other two groups of women, the complication  
15 rates were so much higher and reoperation rates were  
16 so much higher than those other two groups, it's  
17 only going to get higher as time continues to go on.  
18 **Q. And is that significant to you?**  
19 A. Yes.  
20 **Q. And is that one of the bases for the opinion**  
21 **you've just offered us regarding the Prolift?**  
22 A. Yes.  
23 **Q. Okay. Doctor, let's go to the next exhibit,**  
24 **PLT-0011.**  
25 **Can you tell the jury what this**

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1 **document is, please?**  
2 A. This document is a Practice Bulletin that was  
3 published by the American College of Obstetricians  
4 and Gynecologists which is the professional  
5 organization that represents OB/GYN doctors. The  
6 OB/GYN doctors are members of this professional  
7 organization. And so what they do from time to time  
8 is issue these Practice Bulletins which is a summary  
9 of the current available information to provide  
10 clinicians with an update. Busy clinicians don't  
11 read all of the literature all of the time, so this  
12 is provided as a way for them to be aware of what's  
13 currently going on without having to do all the  
14 literature reading themselves.  
15 **Q. All right. Let me stop you there. Is this**  
16 **medically reliable and authoritative, in your**  
17 **opinion?**  
18 A. Yes.  
19 **Q. Is it something you relied on?**  
20 A. Yes.  
21 **Q. What was your involvement in this?**  
22 A. I wrote this.  
23 **Q. And when was it published?**  
24 A. It was published in February 2007.  
25 **Q. And how is it that you came to be asked to**



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<p>- ANNE M. WEBER - DIRECT - Page 89</p> <p>1 <b>author this?</b></p> <p>2 A. The committee on Practice Bulletins Gynecology</p> <p>3 invited me to take a rough draft that had been</p> <p>4 produced by my coauthor who's named on the title</p> <p>5 here, Scott Smilen, who's also a urogynecologist, to</p> <p>6 take a rough draft that he had produced but he had</p> <p>7 been unable to finish, take that and complete the</p> <p>8 project to come up with the final finished bulletin.</p> <p>9 <b>Q. Now, one thing, when you published this, had</b></p> <p>10 <b>you ever spoken to me?</b></p> <p>11 A. No.</p> <p>12 <b>Q. Okay. Now, what I'd like to focus on is on</b></p> <p>13 <b>Page 468.</b></p> <p>14 <b>Your Honor, as Dr. Weber is the</b></p> <p>15 <b>author, is it okay if we publish this?</b></p> <p>16 <b>THE COURT:</b> Yes.</p> <p>17 <b>MR. SLATER:</b> Thank you.</p> <p>18 Put this up. Start with the cover</p> <p>19 first just to orient the jury so they could see</p> <p>20 what it looks like.</p> <p>21 (Document displayed.)</p> <p>22 <b>MR. SLATER:</b> Okay. That's the cover.</p> <p>23 And we're going to go to Page 468, the top right</p> <p>24 corner, the first full paragraph.</p> <p>25 Okay.</p>	<p>- ANNE M. WEBER - DIRECT - Page 91</p> <p>1 able to tell them, okay, this is what you can</p> <p>2 expect, and then the woman can take in that</p> <p>3 information and decide, okay, is this a good thing</p> <p>4 for me or is this not a good thing for me.</p> <p>5 <b>Q. What is the significance of a procedure -- and</b></p> <p>6 <b>would the Prolift fall within this category?</b></p> <p>7 A. Yes.</p> <p>8 <b>Q. What's the significance of a procedure like the</b></p> <p>9 <b>Prolift being experimental? In the real world,</b></p> <p>10 <b>what's that mean?</b></p> <p>11 A. Well, what that means is that it shouldn't be</p> <p>12 used outside of a research setting where the women</p> <p>13 are clearly understanding that they're voluntarily</p> <p>14 participating in a study. Remember we talked about</p> <p>15 this a little earlier. If you already knew the</p> <p>16 answer to the question, you wouldn't have to do the</p> <p>17 study. But since the information isn't there, isn't</p> <p>18 sufficient, if it's not enough, then to get the</p> <p>19 information, women need to be studied. But they do</p> <p>20 that in a voluntary capacity. And there's a whole</p> <p>21 separate consent because, of course, experimenting</p> <p>22 on people without their permission is unethical.</p> <p>23 <b>Q. What factually happened after this was</b></p> <p>24 <b>published?</b></p> <p>25 <b>THE COURT:</b> I'm sorry, when was it</p>
<p>- ANNE M. WEBER - DIRECT - Page 90</p> <p>1 <b>BY MR. SLATER:</b></p> <p>2 <b>Q. What I'll ask you to do, Doctor, you wrote it,</b></p> <p>3 <b>can you just tell the jury what you wrote there.</b></p> <p>4 <b>Can you just read it for the jury?</b></p> <p>5 A. Yes.</p> <p>6 "Given the limited data and frequent</p> <p>7 changes in the marketed products, particularly with</p> <p>8 regard to type of mesh material itself, which is</p> <p>9 most closely associated with several of the</p> <p>10 postoperative risks, especially mesh erosion, the</p> <p>11 procedures should be considered experimental and</p> <p>12 patients should consent to surgery with that</p> <p>13 understanding."</p> <p>14 <b>Q. Why did you say that?</b></p> <p>15 A. I said that because at that point in time -- at</p> <p>16 that point in time there wasn't enough information</p> <p>17 for women to be adequately counseled about what they</p> <p>18 could expect. Remember we talked earlier about</p> <p>19 whenever you're making a decision or, you know, a</p> <p>20 doctor might recommend something to you and you talk</p> <p>21 about what that means, what are the possible ways</p> <p>22 that it could work well for me, what are the</p> <p>23 possible ways it can do badly for me or hurt me.</p> <p>24 And there simply wasn't enough information at that</p> <p>25 point to have -- to adequately counsel women to be</p>	<p>- ANNE M. WEBER - DIRECT - Page 92</p> <p>1 published?</p> <p>2 <b>THE WITNESS:</b> It was published in</p> <p>3 February of 2007.</p> <p>4 <b>MR. SLATER:</b> Thank you, Judge.</p> <p>5 <b>BY MR. SLATER:</b></p> <p>6 <b>Q. What factually, as a matter of fact, what</b></p> <p>7 <b>occurred as a result of this publication? What was</b></p> <p>8 <b>part of the reaction that is significant to you?</b></p> <p>9 A. A small number of members of the American</p> <p>10 College complained about the wording of</p> <p>11 experimental.</p> <p>12 <b>Q. And what's your understanding as to why that</b></p> <p>13 <b>occurred?</b></p> <p>14 <b>MS. ROBINSON:</b> Objection.</p> <p>15 <b>THE COURT:</b> Sustained.</p> <p>16 <b>BY MR. SLATER:</b></p> <p>17 <b>Q. Do you know why that happened?</b></p> <p>18 A. Yes, I do.</p> <p>19 <b>Q. Why did it happen?</b></p> <p>20 <b>MS. ROBINSON:</b> Objection.</p> <p>21 <b>THE COURT:</b> Sustained.</p> <p>22 <b>BY MR. SLATER:</b></p> <p>23 <b>Q. Was there a change made to the word --</b></p> <p>24 A. Yes.</p> <p>25 <b>Q. -- "experimental"?</b></p>



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<p>- ANNE M. WEBER - DIRECT - Page 93</p> <p>1 <b>Why was that change made?</b></p> <p>2 <b>MS. ROBINSON:</b> Objection.</p> <p>3 <b>THE COURT:</b> Sustained.</p> <p>4 <b>BY MR. SLATER:</b></p> <p>5 <b>Q. Do you know why the word "experimental" was</b></p> <p>6 <b>changed, as a matter of fact?</b></p> <p>7 <b>MS. ROBINSON:</b> Objection.</p> <p>8 <b>THE WITNESS:</b> Yes, I do.</p> <p>9 <b>THE COURT:</b> Sustained.</p> <p>10 I think we've covered all the ways</p> <p>11 you can put that same question.</p> <p>12 Next question.</p> <p>13 <b>BY MR. SLATER:</b></p> <p>14 <b>Q. Doctor, after the word was changed, did you --</b></p> <p>15 <b>well, let's go to Exhibit PLT-0506, the next</b></p> <p>16 <b>exhibit.</b></p> <p>17 <b>What is PLT-0506?</b></p> <p>18 A. This is a letter that I -- that was published</p> <p>19 in the literature that I wrote to the editor of the</p> <p>20 International Urogynecology Journal in response</p> <p>21 to --</p> <p>22 <b>MS. ROBINSON:</b> Objection.</p> <p>23 <b>THE COURT:</b> Overruled.</p> <p>24 Continue.</p> <p>25 <b>THE WITNESS:</b> Thank you.</p>	<p>- ANNE M. WEBER - DIRECT - Page 95</p> <p>1 properly be characterized as a conversation</p> <p>2 that's going on in some scientific or medical</p> <p>3 community?</p> <p>4 <b>THE WITNESS:</b> Ummm, personally, I</p> <p>5 think "conversation" may be informal,</p> <p>6 considering this is published in the medical</p> <p>7 literature.</p> <p>8 <b>THE COURT:</b> Okay. What would you</p> <p>9 call it?</p> <p>10 <b>THE WITNESS:</b> I would call it a -- a</p> <p>11 debate.</p> <p>12 <b>THE COURT:</b> Okay. Fair enough.</p> <p>13 Do you have an objection?</p> <p>14 <b>MS. ROBINSON:</b> I do, Your Honor.</p> <p>15 <b>THE COURT:</b> Overruled.</p> <p>16 You may proceed with this article.</p> <p>17 <b>MR. SLATER:</b> Thank you, Your Honor.</p> <p>18 <b>BY MR. SLATER:</b></p> <p>19 <b>Q. So did you write what's on the board, PLT-0506?</b></p> <p>20 A. Yes, I did.</p> <p>21 <b>Q. And it says published September 25, 2009?</b></p> <p>22 A. Yes.</p> <p>23 <b>Q. And you had actually submitted it in August of</b></p> <p>24 <b>'09?</b></p> <p>25 A. Yes.</p>
<p>- ANNE M. WEBER - DIRECT - Page 94</p> <p>1 An article that was written by two</p> <p>2 doctors, a urogynecologist and a medical ethical</p> <p>3 specialist, Drs. Wall and Dr. Brown, in their</p> <p>4 article which was entitled, Commercial Pressures</p> <p>5 and Professional Ethics, Troubling Revisions to</p> <p>6 the Recent ACOG Practice Bulletins on Surgery</p> <p>7 for Pelvic Organ Prolapse.</p> <p>8 <b>THE COURT:</b> Okay. I'm a little bit</p> <p>9 lost.</p> <p>10 Is this what was put up on the screen</p> <p>11 an article that you wrote?</p> <p>12 <b>THE WITNESS:</b> I'm responding to an</p> <p>13 article that Drs. Wall and Brown wrote. And</p> <p>14 this is -- the title is --</p> <p>15 <b>THE COURT:</b> Okay. Whatever was put</p> <p>16 up on the screen, whatever number that is, you</p> <p>17 wrote it?</p> <p>18 <b>THE WITNESS:</b> Yes.</p> <p>19 <b>THE COURT:</b> Okay. And was it</p> <p>20 published anywhere?</p> <p>21 <b>THE WITNESS:</b> Yes.</p> <p>22 <b>THE COURT:</b> Where was it published?</p> <p>23 <b>THE WITNESS:</b> It was published in the</p> <p>24 International Urogynecology Journal.</p> <p>25 <b>THE COURT:</b> Okay. So could this</p>	<p>- ANNE M. WEBER - DIRECT - Page 96</p> <p>1 <b>Q. And does this represent what occurred and what</b></p> <p>2 <b>your viewpoint on that is?</b></p> <p>3 A. Yes.</p> <p>4 <b>Q. Please tell the jury, you can read it to the</b></p> <p>5 <b>jury, what you stated, if that fully states or sets</b></p> <p>6 <b>forth your opinions and view on this.</b></p> <p>7 <b>THE COURT:</b> How about you just tell</p> <p>8 them without reading it.</p> <p>9 <b>THE WITNESS:</b> All right.</p> <p>10 This letter represents -- this letter</p> <p>11 represents what I was told at the time ACOG was</p> <p>12 making the change in the wording of the original</p> <p>13 Practice Bulletin, which was over my objections.</p> <p>14 <b>MS. ROBINSON:</b> Objection, Your Honor.</p> <p>15 <b>THE COURT:</b> Is that what you said</p> <p>16 there? I was told this stuff and therefore...</p> <p>17 <b>THE WITNESS:</b> Yes.</p> <p>18 <b>THE COURT:</b> Okay. Overruled.</p> <p>19 <b>THE WITNESS:</b> I was told by the staff</p> <p>20 member from ACOG representing the committee on</p> <p>21 Practice Bulletins Gynecology that the real</p> <p>22 reason for the change was because physicians</p> <p>23 were concerned that something labeled</p> <p>24 experimental, A, wouldn't be covered by</p> <p>25 insurance. And, B, would expose them to</p>

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<p>- ANNE M. WEBER - DIRECT - Page 97</p> <p>1 medical/legal risk if a complication occurred in 2 the course of these procedures that were labeled 3 "experimental." 4 Now, I felt that that was something 5 that should be seen as a red flag by the 6 organization, the American College, that these 7 clinicians were not concerned about patient 8 safety. They were concerned about what 9 protected their income. And I felt that if ACOG 10 truly was going to stand behind its promise to 11 women as they state in their bylaws, to provide 12 the highest quality of care for women and to 13 maintain the highest standards of clinical 14 practice, then they would not have made this 15 change. 16 Another explanation for why this 17 change was made was that -- 18 <b>THE COURT:</b> Is that in your article? 19 <b>THE WITNESS:</b> Yes. 20 <b>THE COURT:</b> Okay. Keep going. 21 <b>THE WITNESS:</b> -- that ACOG claimed 22 that the meaning of the word "experimental" was 23 not clear to people. 24 Whether or not that was true, if ACOG 25 felt that way, they could have added a</p>	<p>- ANNE M. WEBER - DIRECT - Page 99</p> <p>1 <b>hold that opinion now?</b> 2 A. Yes, I do. 3 <b>Q. Do you have an opinion as to whether or not</b> 4 <b>your decision to describe these kits as experimental</b> 5 <b>was correct, based on that?</b> 6 A. Yes, it was. 7 <b>MR. SLATER:</b> Thank you, Your Honor. 8 <b>THE COURT:</b> Oh, are you finished? 9 <b>MR. SLATER:</b> I am finished. 10 <b>THE COURT:</b> Terrific. 11 Cross-examine. 12 <b>MR. ISMAIL:</b> Time to readjust, Your 13 Honor. 14 <b>THE COURT:</b> Do we need to send the 15 jury out? 16 <b>MS. ROBINSON:</b> It would probably be 17 helpful. 18 <b>MR. SLATER:</b> I used to deliver 19 Sheetrock. I'll get it out of the way. 20 <b>THE COURT:</b> Charles, we'll take a 21 ten-minute recess. 22 <b>COURT CRIER:</b> Yes. 23 Please remain seated until the jury 24 has left the courtroom. 25 Jurors, turn your clipboards over,</p>
<p>- ANNE M. WEBER - DIRECT - Page 98</p> <p>1 clarification to the document itself as far as 2 exactly what was meant; or they could have 3 adopted an official definition of the term 4 "experimental," as other professional 5 organizations have done, like the American 6 Society for Reproductive Medicine. 7 The fact that they didn't do either 8 of these two things underscores their real 9 motivation for why the wording in the bulletin 10 was changed. 11 <b>BY MR. SLATER:</b> 12 <b>Q. As you stand here now, do you have an opinion</b> 13 <b>as to whether or not these mesh kits like the</b> 14 <b>Prolift should have been deemed experimental, as you</b> 15 <b>wrote in the published article?</b> 16 A. Yes, I do. 17 <b>Q. And what's your opinion?</b> 18 A. My opinion is that if they were to be used at 19 all, they should only have been used in the context 20 of an experimental study where women gave their 21 permission to be voluntarily experimented on. 22 <b>Q. And based on your review of the internal</b> 23 <b>documents and the medical literature and all of the</b> 24 <b>information you have with regard to the Prolift and</b> 25 <b>what happened going forward from '07, do you still</b></p>	<p>- ANNE M. WEBER - CROSS - Page 100</p> <p>1 please. Watch your step, please. 2 - - - 3 (Whereupon the jury exited the 4 courtroom at 11:45 a.m.) 5 - - - 6 (Whereupon a recess was taken.) 7 - - - 8 <b>COURT CRIER:</b> Please remain seated as 9 the jury enters the courtroom. 10 - - - 11 (Whereupon the jury entered the 12 courtroom at 11:58 a.m.) 13 - - - 14 <b>COURT CRIER:</b> This court is back in 15 session. 16 <b>THE COURT:</b> Counsel, we're going to 17 go about a half an hour. 18 <b>MS. ROBINSON:</b> Thank you, Your Honor. 19 - - - 20 <b>CROSS-EXAMINATION</b> 21 - - - 22 <b>BY MS. ROBINSON:</b> 23 <b>Q. I guess it's almost good afternoon again.</b> 24 <b>Good afternoon, Ms. Weber. I want to</b> 25 <b>talk to you a little bit further today about your</b></p>

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<p>- ANNE M. WEBER - CROSS - Page 101</p> <p>1 background.</p> <p>2 You are not a licensed Medical</p> <p>3 Doctor; is that correct?</p> <p>4 A. Yes.</p> <p>5 Q. And you are not licensed in any state, correct?</p> <p>6 A. Yes.</p> <p>7 Q. And you haven't been licensed since, what,</p> <p>8 approximately 19 -- or I'm sorry, 2008?</p> <p>9 A. Approximately.</p> <p>10 Q. You are not currently on any staff at any</p> <p>11 hospitals; is that also correct?</p> <p>12 A. Yes.</p> <p>13 Q. You are not board certified today, correct?</p> <p>14 A. I am board certified.</p> <p>15 Q. Do you currently hold a current certificate as</p> <p>16 a practicing member of the Obstetrics and Gynecology</p> <p>17 Society?</p> <p>18 A. I am not practicing clinically, yes, that's</p> <p>19 true.</p> <p>20 Q. You are not and never have been certified as a</p> <p>21 specialist in female pelvic reconstructive surgery;</p> <p>22 is that correct?</p> <p>23 A. Yes.</p> <p>24 Q. And you have not attended any continuing</p> <p>25 medical courses since you gave up your license; is</p>	<p>- ANNE M. WEBER - CROSS - Page 103</p> <p>1 THE COURT: Yes, that's correct; is</p> <p>2 that what you mean?</p> <p>3 THE WITNESS: Yes.</p> <p>4 THE COURT: Yes. Okay.</p> <p>5 BY MS. ROBINSON:</p> <p>6 Q. You've never treated a woman who had a Prolift,</p> <p>7 correct?</p> <p>8 A. That's correct.</p> <p>9 Q. You've never examined a woman who had a</p> <p>10 Prolift, correct?</p> <p>11 A. That's right.</p> <p>12 Q. Prior to being retained as an expert in this</p> <p>13 litigation, you had never seen a surgical video of</p> <p>14 the Prolift surgery, correct?</p> <p>15 A. That's right.</p> <p>16 Q. And also prior to being retained in this</p> <p>17 litigation, you had never observed a Prolift surgery</p> <p>18 with another surgeon; is that correct?</p> <p>19 A. Yes.</p> <p>20 Q. In fact, have you ever observed a Prolift</p> <p>21 surgery with another physician?</p> <p>22 A. No.</p> <p>23 Q. Before being engaged as an expert in this</p> <p>24 litigation, you had not read the Prolift</p> <p>25 Instructions For Use; is that correct?</p>
<p>- ANNE M. WEBER - CROSS - Page 102</p> <p>1 that correct?</p> <p>2 A. Yes.</p> <p>3 Q. Is it also correct that you have not examined a</p> <p>4 patient since the end of 2006?</p> <p>5 A. Yes.</p> <p>6 Q. Is it also fair to say you haven't provided any</p> <p>7 consultation to any patient since that time --</p> <p>8 A. Yes.</p> <p>9 Q. -- in their care and treatment, right?</p> <p>10 Okay. So I also want to ask you a</p> <p>11 few questions now about your experience with</p> <p>12 Prolift. You haven't performed a Prolift surgery,</p> <p>13 correct?</p> <p>14 A. That's right.</p> <p>15 Q. In fact, you quit performing surgeries in 2004,</p> <p>16 right?</p> <p>17 A. That's right.</p> <p>18 Q. And that was before Prolift became [sic] on the</p> <p>19 market?</p> <p>20 A. Yes.</p> <p>21 Q. You had never implanted Prolift in a cadaver?</p> <p>22 A. That's correct.</p> <p>23 Q. You've never attended any professional</p> <p>24 education courses in Prolift, correct?</p> <p>25 A. Yes.</p>	<p>- ANNE M. WEBER - CROSS - Page 104</p> <p>1 A. Yes.</p> <p>2 Q. And you had also not reviewed -- you had not</p> <p>3 participated in any clinical trials involving</p> <p>4 Prolift, correct?</p> <p>5 A. Yes, that's right.</p> <p>6 Q. Now, you're testifying here today as a paid</p> <p>7 expert, correct?</p> <p>8 A. Yes.</p> <p>9 Q. I believe you estimated yesterday that you</p> <p>10 reviewed over a million records?</p> <p>11 A. Yes.</p> <p>12 Q. And you testified also yesterday, I believe,</p> <p>13 that you began working with Mr. Slater in 2010; is</p> <p>14 that correct?</p> <p>15 A. Yes.</p> <p>16 Q. What time in 2010 did you start working with</p> <p>17 him?</p> <p>18 A. February.</p> <p>19 Q. You also mentioned yesterday that you were</p> <p>20 mentoring some medical students?</p> <p>21 A. Yes.</p> <p>22 Q. Does that involve the care and treatment of any</p> <p>23 patients?</p> <p>24 A. No.</p> <p>25 Q. Are you being paid for that position?</p>

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1 A. No.  
 2 **Q. You're testifying here today at a thousand**  
 3 **dollars a day -- or an hour, correct?**  
 4 A. Yes, that's right.  
 5 **Q. Yesterday I believe you mentioned that you also**  
 6 **write some?**  
 7 A. Yes.  
 8 **Q. Have you published any medical literature since**  
 9 **2007?**  
 10 A. I have a commentary that has been submitted for  
 11 publication. It has not yet been published.  
 12 **Q. So fair to say you haven't had a publication on**  
 13 **medical literature since 2007, correct?**  
 14 A. No. No. That's not correct, actually. I  
 15 believe the date was 2011 of my latest peer-reviewed  
 16 publication.  
 17 **Q. And what is that publication?**  
 18 A. That is a reanalysis of the randomized control  
 19 data from my original trial that was published in  
 20 2001, which was a comparison of three different  
 21 surgical techniques for fixing anterior vaginal  
 22 prolapse.  
 23 **Q. Okay. We'll talk about that a little further**  
 24 **later on today.**  
 25 **Is it true, ma'am, that your only**

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1 **source of earned income is working for Mr. Slater?**  
 2 A. Yes.  
 3 **Q. Now, Doctor, we're here to talk today about**  
 4 **prolapse. And I believe you indicated earlier that**  
 5 **there's several different types of native tissue**  
 6 **type repairs; is that correct?**  
 7 A. Suture procedures, yes.  
 8 **Q. And the various kind of suture procedures that**  
 9 **are used, does that depend on the location in the**  
 10 **body where the prolapse has occurred?**  
 11 A. Yes.  
 12 **Q. So for a cystocele, what are the options? And**  
 13 **that's the bladder prolapse, right?**  
 14 A. Yes.  
 15 So a cystocele representing prolapse  
 16 of the anterior vagina, with the bladder behind it,  
 17 can be treated surgically by an anterior  
 18 colporrhaphy, sometimes called an anterior repair.  
 19 And another alternative would be a paravaginal  
 20 repair, also done through the vagina. And another  
 21 alternative would be what's called a site-specific  
 22 anterior repair.  
 23 **Q. And those are the three types of native tissue**  
 24 **for repairing bladder prolapse?**  
 25 A. Yes.

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1 **Q. Other than those three types of surgical**  
 2 **procedures, before Prolift became on the market,**  
 3 **were there other repairs for a bladder prolapse?**  
 4 A. Yes.  
 5 **Q. And what was that?**  
 6 A. A surgeon could decide to use a different  
 7 product. There are a number of kinds of products.  
 8 We touched on this just briefly yesterday. A  
 9 biologic, so that could be cadaveric tissue, you  
 10 know, taken from a cadaver and processed; or what's  
 11 called a xenograft, which is tissue that's been  
 12 harvested from an animal, sometimes a pig or a  
 13 sheep, and processed; or a synthetic mesh, manmade  
 14 mesh. The surgeon could choose one that's fully  
 15 absorbable, partially absorbable, or fully  
 16 permanent.  
 17 **Q. Okay. So those grafts that you just mentioned**  
 18 **plus the three types of surgery is what was**  
 19 **available as surgical options prior to Prolift,**  
 20 **correct?**  
 21 A. Yes.  
 22 **Q. Now, with respect to the three surgical**  
 23 **options, do you agree, Doctor, that there were**  
 24 **different techniques that individual surgeons would**  
 25 **use to perform those surgeries?**

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1 A. Yes.  
 2 **Q. And would you agree that often the outcomes of**  
 3 **those surgeries depended on the type of technique**  
 4 **that was used by the individual doctor?**  
 5 A. It could be, yes.  
 6 **Q. Now, these repairs, they involved the use of**  
 7 **sutures, correct?**  
 8 A. Yes.  
 9 **Q. And the sutures were used to bring the tissue**  
 10 **back in together and sewed it up, basically?**  
 11 A. Basically, yes.  
 12 **Q. And they did that to repair tissue that had**  
 13 **already been weakened, correct?**  
 14 A. Yeah. To answer that with a yes or no is  
 15 not -- it would be incomplete.  
 16 **Q. You can't answer that with a yes or a no?**  
 17 A. In -- basically. I'll accept that.  
 18 **Q. Basically that's true, right?**  
 19 A. (Witness nodding.)  
 20 **THE COURT:** If you want her to answer  
 21 completely, it's going to have to be a yes-or-no  
 22 question.  
 23 Do you want her to answer or do you  
 24 want to move on?  
 25 **MS. ROBINSON:** I'm ready to move on.



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<p>- ANNE M. WEBER - CROSS - Page 109</p> <p>1 THE COURT: Okay. That's fine.</p> <p>2 BY MS. ROBINSON:</p> <p>3 Q. So the tissues that we have just discussed that</p> <p>4 have been weakened, they were weakened by things</p> <p>5 like childbirth, correct?</p> <p>6 A. Yes, that's possible.</p> <p>7 Q. Age?</p> <p>8 A. Yes.</p> <p>9 Q. Menopause or lack of estrogen?</p> <p>10 A. Possibly.</p> <p>11 Q. Why do you hesitate on that one?</p> <p>12 A. Age and menopause are inextricably linked.</p> <p>13 Very difficult to tease that apart in research.</p> <p>14 Q. Do you agree that these tissues, there's</p> <p>15 factors that can aggravate the weakened tissues to</p> <p>16 extend the weakness, to make it progress?</p> <p>17 A. Possibly.</p> <p>18 Q. And do you agree that that would include things</p> <p>19 like heavy lifting or activities that would strain</p> <p>20 the abdominal walls?</p> <p>21 A. Possibly. And that's an anecdote -- anecdotal</p> <p>22 information that we as surgeons have carried for</p> <p>23 decades. Recent literature actually does not bear</p> <p>24 that out.</p> <p>25 Q. So one of the problems of these native tissue</p>	<p>- ANNE M. WEBER - CROSS - Page 111</p> <p>1 see recurrence rates reflected for the treated</p> <p>2 compartment?</p> <p>3 A. Yes.</p> <p>4 Q. And then you also sometimes see them</p> <p>5 referencing a recurrence in an untreated</p> <p>6 compartment; is that correct?</p> <p>7 A. Yes.</p> <p>8 Q. Now, which one of those do you subscribe is the</p> <p>9 best way to analyze the data?</p> <p>10 A. The best way to represent outcomes of prolapse</p> <p>11 surgery are the outcomes of most importance to</p> <p>12 women. And I think we mentioned this a little bit</p> <p>13 earlier, that prolapse comes and it may be fixed by</p> <p>14 surgery and may come back.</p> <p>15 Women don't ordinarily distinguish</p> <p>16 between the anterior vagina, the apical vagina, the</p> <p>17 posterior vagina. Those are distinctions that</p> <p>18 doctors make. Prolapse is prolapse for a woman.</p> <p>19 So the outcome of greatest importance</p> <p>20 to women being the existence of prolapse. That</p> <p>21 would be one of the more important outcomes in</p> <p>22 research.</p> <p>23 Q. Do you agree, Doctor, that in the year 2000,</p> <p>24 the anatomic failure rate for anterior colporrhaphy</p> <p>25 was approximately 40 percent?</p>
<p>- ANNE M. WEBER - CROSS - Page 110</p> <p>1 repairs was the high recurrence rate; is that</p> <p>2 correct?</p> <p>3 A. The recurrence rate -- well, yes, I'll just say</p> <p>4 yes.</p> <p>5 Q. And when we say high recurrence rate, could you</p> <p>6 tell the members of the jury what you mean by</p> <p>7 recurrence rate?</p> <p>8 A. So recurrence, like we talked a little bit</p> <p>9 about before, is when the prolapse comes back. And</p> <p>10 in a perfect world, that would never happen. But</p> <p>11 since we're not in a perfect world, that does happen</p> <p>12 to a certain degree.</p> <p>13 Q. When you say it comes back, are we generally</p> <p>14 speaking about it coming back in the compartment</p> <p>15 that was treated?</p> <p>16 A. Not necessarily.</p> <p>17 Q. So the word "recurrence" could be used for</p> <p>18 multiple things, for multiple -- I'm sorry. Strike</p> <p>19 that. Let me reask the question.</p> <p>20 The term "recurrence," can it be</p> <p>21 referred to failure in both the compartment that's</p> <p>22 treated as well as a compartment of the woman's</p> <p>23 body, the organs that haven't been treated?</p> <p>24 A. Yes.</p> <p>25 Q. So in scientific literature, do you sometimes</p>	<p>- ANNE M. WEBER - CROSS - Page 112</p> <p>1 A. Yes.</p> <p>2 Q. And, in fact, you wrote about that; is that</p> <p>3 correct?</p> <p>4 A. Yes.</p> <p>5 Q. And the 2011 [sic] study that you just</p> <p>6 indicated that you had reanalyzed in 2011, you first</p> <p>7 published it around the year 2000; is that correct?</p> <p>8 A. I'm sorry. I may not be understanding your</p> <p>9 question. Are you asking the publication date of</p> <p>10 the original randomized trial?</p> <p>11 Q. Yes.</p> <p>12 A. Yes. That was in 2001.</p> <p>13 (Handing document to the witness.)</p> <p>14 (Pause.)</p> <p>15 MS. ROBINSON: Sorry about the delay,</p> <p>16 Your Honor.</p> <p>17 BY MS. ROBINSON:</p> <p>18 Q. So, ma'am, in 2001 you published a study called</p> <p>19 Anterior Colporrhaphy, a Randomized Trial of Three</p> <p>20 Surgical Techniques; is that correct?</p> <p>21 A. Yes.</p> <p>22 Q. And in that study did you enroll about 114</p> <p>23 patients?</p> <p>24 A. Yes.</p> <p>25 Q. When you analyzed the data, is it correct,</p>

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<p>- ANNE M. WEBER - CROSS - Page 113</p> <p>1 ma'am, that only 109 patients were available to 2 reanalyze the data?</p> <p>3 A. I'm sorry, I don't understand your question.</p> <p>4 Q. When you analyzed the data from these patients, 5 is it correct that only 109 patients returned for 6 follow-up?</p> <p>7 A. No.</p> <p>8 Q. Is it correct that only 109 patients returned 9 for follow-up approximately 23.3 months after the 10 surgery when you reported the data?</p> <p>11 A. I'm sorry. We may be having a 12 miscommunication. Are you referring to the 13 reanalysis of the original 2001 trial?</p> <p>14 Q. I'm referring to the analysis of this trial. 15 And you're right, maybe I misspoke. 16 You originally enrolled 114 patients, 17 right?</p> <p>18 A. Yes.</p> <p>19 Q. And for some reason only 109 patients underwent 20 surgery?</p> <p>21 A. Yes.</p> <p>22 Q. And of those 109 patients, then you only had 83 23 patients that returned for follow-up that was 24 reported on in your study; is that also correct?</p> <p>25 A. Yes.</p>	<p>- ANNE M. WEBER - CROSS - Page 115</p> <p>1 them do not return to the original surgeon. That's 2 my testimony.</p> <p>3 Q. And have you taken that testimony one step 4 further to say that that indicates that these 5 individuals did not have a good outcome? Is that 6 your testimony?</p> <p>7 A. No.</p> <p>8 Q. That's not your testimony, right?</p> <p>9 A. (Shaking head.)</p> <p>10 THE COURT: Right. That's what she 11 just said.</p> <p>12 Next question.</p> <p>13 BY MS. ROBINSON:</p> <p>14 Q. In your study, the 24 percent of the patients 15 that weren't able to be evaluated, how did you 16 consider their outcomes?</p> <p>17 A. (Pause.)</p> <p>18 Okay. They were simply treated as 19 missing data.</p> <p>20 Q. Which means you didn't know what their 21 particular outcomes were; is that correct?</p> <p>22 A. That's right.</p> <p>23 Q. So with respect to the patients that did have 24 data, is it correct that you found failure rates 25 that ranged from 54 to 70 percent?</p>
<p>- ANNE M. WEBER - CROSS - Page 114</p> <p>1 Q. So that's about 24 percent of your patients 2 that were lost to follow-up, correct?</p> <p>3 A. That is correct.</p> <p>4 Q. Now, when I heard you testify earlier today, 5 you told this jury that if patients didn't return 6 for follow-up, that means they had a bad outcome; is 7 that right?</p> <p>8 A. I'm sorry?</p> <p>9 Q. Did you tell this jury today that when patients 10 were lost to follow-up for studies, that was a good 11 indication that they had had a bad outcome?</p> <p>12 A. No, I don't believe I testified to that.</p> <p>13 Q. What did you tell the jury today about the loss 14 to follow-up, if patients were lost to follow-up and 15 not available to be evaluated?</p> <p>16 A. What we know in the literature related 17 specifically to mesh kits is that when women 18 experience complications, they may not return to the 19 implanting surgeon and they may instead seek care at 20 another institution.</p> <p>21 Q. So this is a phenomenon that's reserved for 22 mesh kits; is that what your testimony is, ma'am?</p> <p>23 A. My testimony is that the literature, the recent 24 literature describing complications in women after 25 receiving a mesh kit is that a high proportion of</p>	<p>- ANNE M. WEBER - CROSS - Page 116</p> <p>1 A. Yes, that's right.</p> <p>2 Q. So 54 to 70 percent of the women who underwent 3 your study had failure rates within two years of the 4 surgery; is that correct?</p> <p>5 A. Yes, that's right.</p> <p>6 Q. And you calculated the failure rates based on 7 an anatomical cure; is that also correct?</p> <p>8 A. Yes.</p> <p>9 Q. And you calculated any failures for anyone who 10 had a Stage II or greater after surgery; is that 11 correct?</p> <p>12 A. Yes, that's right.</p> <p>13 Q. Is it also correct that you only analyzed that 14 with respect to the treated compartment, that being 15 the anterior compartment?</p> <p>16 A. (No response.)</p> <p>17 Q. If you want to look on Page 2 in the right-hand 18 column down in the middle of it where it says "cure 19 was defined."</p> <p>20 A. Yes.</p> <p>21 Q. So if I understand this study correctly, three 22 different types of surgery were used to correct a 23 woman's prolapsed bladder, correct?</p> <p>24 A. Anterior vaginal prolapse, yes.</p> <p>25 Q. You performed the surgeries; and based on</p>

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<p>- ANNE M. WEBER - CROSS - Page 117</p> <p>1 failures in the treated compartment, that being the</p> <p>2 compartment, the bladder, correct?</p> <p>3 A. Yes.</p> <p>4 Q. Based on that, you had lost -- you had failure</p> <p>5 rates of 54 to 70 percent, correct?</p> <p>6 A. Yes.</p> <p>7 Q. You also noticed -- you noted in the study that</p> <p>8 this was the first randomized control trial that had</p> <p>9 assessed anterior colporrhaphy surgeries; is that</p> <p>10 correct?</p> <p>11 A. Yes, that's right.</p> <p>12 Q. Now, anterior colporrhaphies had been around</p> <p>13 for hundreds of years, right?</p> <p>14 A. Yes.</p> <p>15 Q. And this is the first time that it had been</p> <p>16 assessed in a randomized control trial for the</p> <p>17 treatment of prolapse?</p> <p>18 A. Yes, that's right.</p> <p>19 Q. So you had been practicing medicine for about</p> <p>20 13 years before this anterior colporrhaphy had ever</p> <p>21 been studied through a randomized control trial,</p> <p>22 correct?</p> <p>23 A. Roughly, yes.</p> <p>24 Q. And you had been performing that surgery</p> <p>25 yourself, right?</p>	<p>- HAMMONS -vs- ETHICON, et al. - Page 119</p> <p>1 until the jury has left the courtroom.</p> <p>2 Jurors, follow me. Turn your</p> <p>3 clipboards over.</p> <p>4 - - -</p> <p>5 (Whereupon the jury exited the</p> <p>6 courtroom at 12:23 p.m.)</p> <p>7 - - -</p> <p>8 <b>THE COURT:</b> Counsel, I understand</p> <p>9 that we have an objection to the deposition of</p> <p>10 Aaron Kirkemo hanging. Is there anything else</p> <p>11 that's hanging?</p> <p>12 <b>MR. ISMAIL:</b> Your Honor, the</p> <p>13 designation of Dr. Hinoul relates to the very</p> <p>14 same e-mail, so...</p> <p>15 <b>THE COURT:</b> Okay. Do we have that</p> <p>16 deposition that I can look at? Or bring it --</p> <p>17 after lunch give me that and let me know what</p> <p>18 the problem is.</p> <p>19 Is there anything else that's</p> <p>20 hanging?</p> <p>21 (No response.)</p> <p>22 <b>THE COURT:</b> Is there anything else we</p> <p>23 need to deal with or can productively deal with</p> <p>24 at this time?</p> <p>25 (No response.)</p>
<p>- ANNE M. WEBER - CROSS - Page 118</p> <p>1 A. Yes.</p> <p>2 Q. And it was not supported with data that would</p> <p>3 be of a Level I type data, correct?</p> <p>4 A. That's right.</p> <p>5 Q. And that's the highest data -- you as a trained</p> <p>6 statistician know that that's the highest kind of</p> <p>7 data that you can have to assess a person's outcome;</p> <p>8 is that correct?</p> <p>9 A. I wouldn't word it like that. I would say it's</p> <p>10 the trial design that allows you to compare groups</p> <p>11 and their outcomes and actually assign a cause and</p> <p>12 effect to the outcomes.</p> <p>13 Q. And moving on to 2004 --</p> <p>14 <b>THE COURT:</b> If you're moving off this</p> <p>15 article, it's time to break for lunch.</p> <p>16 <b>MS. ROBINSON:</b> Yes, Your Honor.</p> <p>17 Thank you.</p> <p>18 <b>THE COURT:</b> Okay. Ladies and</p> <p>19 gentlemen of the jury, we're going to break for</p> <p>20 lunch at this time. I'll ask you to return at</p> <p>21 ten minutes to 2:00. Between now and when you</p> <p>22 return, keep an open mind and don't discuss the</p> <p>23 case with anyone.</p> <p>24 Charles.</p> <p>25 <b>COURT CRIER:</b> Please remain seated</p>	<p>- HAMMONS -vs- ETHICON, et al. - Page 120</p> <p>1 <b>THE COURT:</b> Then we stand in recess</p> <p>2 until ten minutes to 2:00.</p> <p>3 <b>MR. ISMAIL:</b> Thank you, Your Honor.</p> <p>4</p> <p>5 (Morning Session concluded.)</p> <p>6 - - -</p> <p>7 (Luncheon recess was taken.)</p> <p>8 - - -</p> <p>9 (Whereupon the Afternoon Session was</p> <p>10 reported and transcribed by Judith Ann Romano,</p> <p>11 CRR, Official Court Reporter.)</p> <p>12 - - -</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>

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CERTIFICATION

I hereby certify that the proceedings and evidence are contained fully and accurately in the notes taken by me on the trial of the above cause, and that this copy is a correct transcript of the same.

I further certify that I am not a relative or employee of any attorney or counsel employed in this case.

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John J. Kurz, RMR, CRR  
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IN THE COURT OF COMMON PLEAS OF PHILADELPHIA COUNTY  
FIRST JUDICIAL DISTRICT OF PENNSYLVANIA  
CIVIL TRIAL DIVISION

IN RE: PELVIC MESH LITIGATION:

PATRICIA HAMMONS, : MAY TERM, 2013  
Plaintiff:

v.

ETHICON, INC., et al., :  
Defendants : NO. 3913

Tuesday, December 8, 2015

COURTROOM 246  
CITY HALL  
PHILADELPHIA, PENNSYLVANIA

B E F O R E: THE HONORABLE MARK I. BERNSTEIN, J.,  
and a Jury

JURY TRIAL VOLUME VI

AFTERNOON SESSION

REPORTED BY:  
JUDITH ANN ROMANO, CM, CRR  
CERTIFIED MERIT REPORTER  
CERTIFIED REALTIME REPORTER  
OFFICIAL COURT REPORTER

A P P E A R A N C E S: (Continued)

GOLDMAN, ISMAIL, TOMASELLI, BRENNAN & BAUM, LLP  
BY: TAREK ISMAIL, ESQUIRE  
(admitted pro hac vice)  
564 West Randolph Street, Suite 400  
Chicago, Illinois 60661  
T: 312-681-6000 F: 312-881-5190  
E-mail: tismail@goldmanismail.com  
Counsel for Defendants Ethicon and Johnson and  
Johnson

THOMAS COMBS & SPANN, PLLC  
BY: SUSAN M. ROBINSON, ESQUIRE  
(admitted pro hac vice)  
300 Summers Street, Suite 1380  
Charlestown, WV 25338  
T: 304-414-1800 F: 304-414-1801  
Counsel for Defendants Ethicon and Johnson and  
Johnson

A P P E A R A N C E S:

KLINE & SPECTER, A Professional Corporation  
BY: SHANIN SPECTER, ESQUIRE  
BY: KILA B. BALDWIN, J.D., ESQUIRE  
1525 Locust Street  
The Nineteenth Floor  
Philadelphia, Pennsylvania 19102  
T: 215-772-1000 F: 215-735-0937  
E-mail: shanin.specter@klinespecter.com  
kila.baldwin@klinespecter.com  
Counsel for Plaintiff Hammons

MAZIE, SLATER, KATZ & FREEMAN  
BY: ADAM M. SLATER, ESQUIRE  
103 Eisenhower Parkway  
Roseland, New Jersey 07068  
T: 973-228-0454 F: 973-228-0303  
E-mail: aslater@mskf.net  
Counsel for Plaintiff Hammons

DRINKER BIDDLE & REATH, LLP  
BY: MOLLY E. FLYNN, ESQUIRE  
One Logan Square, Suite 2000  
Philadelphia, Pennsylvania 19103-6996  
T: 215-988-2836 F: 215-988-2757  
E-mail: molly.flynn@dbrr.com  
Counsel for Defendants Ethicon and Johnson and  
Johnson

TUCKER ELLIS, LLP  
BY: MATTHEW P. MORIARTY, ESQUIRE  
950 Main Avenue, Suite 1100  
Cleveland, Ohio 44113-7213  
T: 216-696-2276 F: 216-592-5009  
E-mail: matthew.moriarty@tuckerellis.com  
Counsel for Defendants Ethicon and Johnson and  
Johnson

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1 (Hearing is reconvened at 1:48 p.m.)

2 (ANNE MARGARET WEBER, MD, having been

3 previously sworn, resumes the witness stand.)

4 THE COURT: Is this another deposition?

5 MS. ISMAIL: Your Honor, that is the

6 Dr. Hinoul deposition I mentioned before

7 lunch, just the part I marked is the exchange

8 regarding the E-mail that was in the Kirkemo

9 deposition.

10 THE COURT: Same E-mail?

11 MS. ISMAIL: Same E-mail, same issue.

12 THE COURT: So it's the same objection,

13 really?

14 MS. ISMAIL: Yes, Your Honor.

15 THE COURT: Great, thank you.

16 MS. ISMAIL: And I understand it's not

17 ripe for today.

18 THE COURT: Whenever people want me to

19 decide it, we will talk about it.

20 MS. ISMAIL: Great, thank you.

21 THE COURT: But I will read this to see

22 if it's the same.

23 MS. ISMAIL: Thank you.

24 THE COURT: So I understand there is a

25

**(Weber - Cross)** Page 127

1 juror or two in the restroom and as soon as

2 they are ready -- they are coming in? They

3 are coming in.

4 (The jury enters the courtroom at 1:58

5 p.m.)

6 THE COURT: Good afternoon, ladies and

7 gentlemen.

8 JURY: Good afternoon.

9 THE COURT: You may proceed.

10 MS. ROBINSON: Thank you, Your Honor.

11 - - -

12 CROSS-EXAMINATION (Continuing)

13 - - -

14 BY MS. ROBINSON:

15 Q Doctor, we had just been discussing some of

16 the high recurrence rates associated with the tissue

17 repairs for bladder prolapse, correct?

18 **A Yes.**

19 Q You continued to follow women who were

20 undergoing surgery for bladder repair by native

21 tissue; is that correct?

22 **A In this trial? Is that what you mean?**

23 Q No, you continued even after the last trial

24 that we were talking about, where you did the study

25

**(Weber - Cross)** Page 128

1 with the three arms?

2 **A Yes.**

3 Q You continued to study it even further, right?

4 **A I am sorry, I don't understand your question.**

5 **Do you mean did we continue to follow that group of**

6 **women?**

7 Q No, no, the issue.

8 **A Oh, just the issue itself. Yes.**

9 Q Yes, the issue of women undergoing surgery for

10 bladder prolapse using native tissue repair, you

11 continued to study that problem; is that correct?

12 **A Yes.**

13 Q And you continued to find that in some of your

14 studies that as much as 58 percent of women would

15 have recurrence within one year; is that correct?

16 **A Not restricted to anterior vaginal prolapse,**

17 **but, yes, correct.**

18 Q And that would be a study you reported on in

19 2004; is that correct?

20 **A Yes.**

21 Q Do you agree with what you stated back then,

22 that, "Recurrent poly-organ prolapse after surgical

23 correction is one of the most vexing problems in

24 reconstructive pelvic surgery"?

25

**(Weber - Cross)** Page 129

1 **A Yes.**

2 Q You continue to agree with that?

3 **A Yes.**

4 Q Now as a result of these high recurrence rates

5 that doctors were seeing, did that lead doctors to

6 begin looking at other options for more durable

7 repairs?

8 **A Yes.**

9 Q And in fact, in the late 1990s, 2000, maybe

10 even earlier than that, they started using synthetic

11 mesh in pelvic organ prolapse repair; is that

12 correct?

13 **A Yes.**

14 Q And they were doing the abdominal

15 sacrocolpopexy, or the ASC that I probably should

16 just call it, surgery for that; is that correct?

17 **A Yes. Actually, I mean ASC preceded the use of**

18 **synthetic mesh through the vagina by a good number**

19 **of years, but, yes.**

20 Q And ASC, though, repair started using mesh,

21 correct?

22 **A Yes.**

23 Q And the reason for that was to reinforce that

24 native tissue to help preclude recurrence, correct?

25

1 (Weber - Cross) Page 130

2 **A The need for the use of --**

3 Q Is that a yes or no?

4 **A No.**

5 Q The ASC surgery is done for an apical repair,

6 correct?

7 **A Yes.**

8 Q And what kind of repair is that?

9 **A An apical repair, just to make sure I**

10 **understand, are you asking me to describe the ASC or**

11 **the indications for the ASC?**

12 Q The apical. What are you trying to repair

13 with the ASC?

14 **A Okay, thank you. The abdominal sacrocolpopexy**

15 **is used to support the apex or the top of the vagina**

16 **in a woman who has her uterus and cervix, which can**

17 **be preserved at that time, or in a woman who has had**

18 **a previous hysterectomy and prolapse has affected**

19 **the top of the vagina so it begins to fall down, if**

20 **you will, inside the vagina at an earlier stage and**

21 **can actually protrude outside the vagina at a later**

22 **stage.**

23 Q And in order to perform that surgery, a woman

24 has to be put under, correct?

25 **A (No response.)**

1 (Weber - Cross) Page 131

2 Q Anesthesia?

3 **A Anesthesia is required, that's right.**

4 Q She is on an operating table and a surgeon

5 will cut an incision in her stomach, correct?

6 **A That's one method of performing it, yes.**

7 Q So with the abdominal sacrocolpopexy, not

8 using laparoscopic, we are not talking about

9 laparoscopic, but with that procedure, it is a

10 surgical incision, correct?

11 **A Yes.**

12 Q The surgeon then goes down in through all of

13 the muscles and so forth in the abdomen to get to

14 the area that he needs to be in to repair and

15 support the vagina, correct?

16 **A Yes. The muscles aren't cut, they are simply**

17 **separated.**

18 Q There are some women that, because of the risk

19 of that type of surgery, can't undergo that surgery;

20 is that correct?

21 **A Yes.**

22 Q This might be older women?

23 **A Rarely. Yes.**

24 Q Women that have chronic problems that would

25 make it difficult for them to undergo anesthesia?

1 (Weber - Cross) Page 132

2 **A Again, rarely. Yes.**

3 Q Now the doctors then began using mesh in the

4 vaginal area, correct?

5 **A Yes.**

6 Q And long before doctors started using mesh in

7 the vaginal area, vaginal surgeries were fairly

8 predominant, correct?

9 **A I am sorry, I don't understand your question.**

10 Q So doctors, before they started using mesh for

11 repairs through the vagina for pelvic organ

12 prolapse, those doctors were already familiar with

13 operating in the vaginal area, correct?

14 **A Yes.**

15 Q They were performing vaginal hysterectomies,

16 right?

17 **A Yes.**

18 Q And other procedures such as that that

19 would -- the route of injury would be through the

20 vagina, correct?

21 **A Yes.**

22 Q And one of the methods that they started or

23 one of the conditions that they started using mesh

24 to help cure was stress urinary incontinence,

25 correct?

1 (Weber - Cross) Page 133

2 **A Yes.**

3 Q And many manufacturers began making mesh for

4 that treatment of that condition, correct?

5 **A Yes.**

6 Q And this was before mesh became available,

7 synthetic mesh became available for pelvic organ

8 prolapse. Is that also correct?

9 **A Yes.**

10 Q Now, you talked a little bit yesterday about

11 the material Gynemesh PS; is that right?

12 **A Yes.**

13 Q Isn't it a fact that you have actually used

14 synthetic mesh for the treatment of stress urinary

15 incontinence?

16 **A Yes.**

17 Q And isn't it correct that when you have

18 written about options for surgery to treat stress

19 urinary incontinence, you have written favorably

20 about the use of mesh to treat stress urinary

21 incontinence?

22 **A If there is a specific article that you are**

23 **referring to, I would like to see it.**

24 MS. ROBINSON: May I approach, Your

25 Honor?

1 (Weber - Cross) Page 134

2 THE COURT: Charles will be happy to

3 pass up anything you'd like.

4 MS. ROBINSON: I do, and I would note

5 it for the record.

6 So for the record, Your Honor, this is

7 Defense 31554.1. And I would also move as an

8 exhibit the -- or just mark the last exhibit

9 that I entered, and we will make the record

10 clear on that.

11 THE COURT: How are we marking it?

12 MS. ROBINSON: It's marked and --

13 THE COURT: Okay, how is it marked

14 then?

15 MS. ROBINSON: It is Defense 31576.1.

16 Thank you.

17 THE COURT: Have you had a chance to

18 look at this exhibit?

19 THE WITNESS: I am looking at it just

20 now.

21 THE COURT: Let's hear a question,

22 maybe that will help you. Ask a question, and

23 then you look at it if you need to.

24 Q Does that publication refresh your memory

25 about a writing that you did on sling options for

1 (Weber - Cross) Page 135

2 stress urinary incontinence patients?

3 **A Yes. I was a co-author on this publication.**

4 Q And in that article do you discuss that, "The

5 evolution of SUI surgeries have shifted so far

6 toward mid-urethral slings that Burch

7 colposuspension and the pure vaginal sling are

8 rarely performed or taught in Obstetrics and

9 Gynecology." Is that correct?

10 **A Yes, I did write that.**

11 Q When you are talking about the slings that

12 were used in that stress urinary incontinence

13 surgery, you were talking about polypropylene mesh;

14 is that correct?

15 **A Yes.**

16 Q And you were talking about slings such as

17 Ethicon's TPT; is that correct?

18 **A Yes.**

19 Q And when you were doing that do you recall

20 referring to them as "lightweight," large-pore mesh?

21 **A Yes.**

22 Q Would you agree with me that the Gynemesh PS,

23 the mesh that is used in Prolift, has larger pores

24 than Ethicon's TVT?

25 **A No.**

1 (Weber - Cross) Page 136

2 Q You would not?

3 **A No.**

4 Q Do you agree with me that it's slightly

5 lighter weight?

6 **A Yes.**

7 Q Do you agree with me that the pore size is

8 approximately the same?

9 **A No.**

10 Q So you discussed yesterday the Prolift plus M.

11 Do you recall talking with Plaintiff's counsel about

12 that?

13 **A (No response.)**

14 Q Generally, do you recall discussing Prolift

15 plus M yesterday?

16 **A Honestly, I don't, but undoubtedly I did if**

17 **you are referring to it.**

18 Q Do you recall talking about Ultrapro?

19 **A Yes.**

20 Q Ultrapro mesh. And Ultrapro mesh is the mesh

21 that is used for the product Prolift plus M?

22 **A Yes.**

23 Q And that mesh is made of polypropylene with an

24 absorbable type of material; is that correct?

25 **A Yes.**

1 (Weber - Cross) Page 137

2 Q And that product is also used for pelvic organ

3 prolapse; is that correct?

4 **A Yes.**

5 Q And you know that it was considered as a

6 potential use for Prolift, correct?

7 **A Yes.**

8 Q And at the time, it had not been fully

9 evaluated, when Ethicon put Prolift on the market;

10 is that correct?

11 **A Yes.**

12 Q Now I just want the jury to know, Ma'am, do

13 you think it's okay to use any kind of synthetic

14 mesh for the repair of pelvic organ prolapse through

15 the vagina?

16 **A No.**

17 Q Now you are interested in the area of the

18 literature and the material surrounding pelvic organ

19 prolapse and that condition; is that correct?

20 **A Yes.**

21 Q And you keep up with it even today, correct?

22 **A Yes.**

23 Q And you have read literature currently about

24 Prolift plus M; is that correct?

25 **A Yes.**

<p>1 (Weber - Cross) Page 138</p> <p>2 Q Or Ultrapro?</p> <p>3 A Yes.</p> <p>4 Q And do you agree with me that some of that</p> <p>5 literature would indicate that up to 14.8 percent of</p> <p>6 women undergoing the use of pelvic organ repair with</p> <p>7 Ultrapro has a risk of mesh erosions?</p> <p>8 A I am sorry, could you repeat that?</p> <p>9 Q Yes, I will try.</p> <p>10 THE COURT: Does the literature show</p> <p>11 that there is a risk of mesh erosion up to</p> <p>12 14 percent or a little more than that?</p> <p>13 THE WITNESS: With the Prolift plus M,</p> <p>14 yes.</p> <p>15 Q And do you also agree with me that there is</p> <p>16 literature that shows that with Prolift plus M there</p> <p>17 is up to 9 percent risk of dyspareunia or pain with</p> <p>18 sex?</p> <p>19 A If you are referring to a specific article, I</p> <p>20 would like to see it.</p> <p>21 THE COURT: Well, do you know, without</p> <p>22 referring to an article?</p> <p>23 THE WITNESS: I do not know that</p> <p>24 figure, the 9 percent.</p> <p>25 THE COURT: Okay, next question.</p>	<p>1 (Weber - Cross) Page 140</p> <p>2 A That's a very good question, and something</p> <p>3 that has been studied, without a definitive answer.</p> <p>4 By the beginning of early Stage III,</p> <p>5 which is in POP U system where the vagina is</p> <p>6 protruding outside of the hymen by more than one</p> <p>7 centimeter, one centimeter is like half an inch,</p> <p>8 roughly, women may become aware of that. Now, of</p> <p>9 course, awareness is not necessarily a negative</p> <p>10 impact on their quality of life. And there isn't a</p> <p>11 linear relationship, there is not a straight line</p> <p>12 between the degree of prolapse and women's awareness</p> <p>13 or being bothered by, whether or not they are aware</p> <p>14 of the prolapse.</p> <p>15 Q So women that have a Stage II prolapse, for</p> <p>16 example, would you say that most of them are not</p> <p>17 symptomatic with prolapse?</p> <p>18 A No, I wouldn't say most.</p> <p>19 Q Do you agree that most women that have Stage</p> <p>20 II prolapse can still have a good quality of life?</p> <p>21 A You are speaking, I assume, specifically</p> <p>22 health-related quality of life specific to her</p> <p>23 prolapse?</p> <p>24 Q Correct.</p> <p>25 A Again, I wouldn't say most, but certainly that</p>
<p>1 (Weber - Cross) Page 139</p> <p>2 Q How high of a figure do you think the</p> <p>3 dyspareunia rates have shown for Ultrapro?</p> <p>4 A I can't pull that off the top of my head.</p> <p>5 THE COURT: Why don't we move on while</p> <p>6 you are trying to find that article.</p> <p>7 Q Doctor, if you will just take a review of</p> <p>8 Defense 30989.1. And I want you to look at -- if</p> <p>9 you look on the right-hand column there, to make it</p> <p>10 a little bit easier for you, where it talks about</p> <p>11 the de novo dyspareunia rates?</p> <p>12 A Yes.</p> <p>13 Q And does this refresh your memory that there</p> <p>14 have been presentations presented that would show</p> <p>15 dyspareunia rates up to 9 percent involving</p> <p>16 Ultrapro?</p> <p>17 A In this one abstract, yes.</p> <p>18 Q Now you have testified here today that quality</p> <p>19 of life is one of the important factors in</p> <p>20 determining success of a prolapse surgical</p> <p>21 procedure; is that correct?</p> <p>22 A Yes.</p> <p>23 Q Do you have an opinion as to what stage of</p> <p>24 prolapse would have to exist in order for a woman to</p> <p>25 have a negative impact on her quality of life?</p>	<p>1 (Weber - Cross) Page 141</p> <p>2 occurs.</p> <p>3 Q Recently when you have assessed and studied</p> <p>4 pelvic organ prolapse, where does the staging fall</p> <p>5 into your determination of how you assess here?</p> <p>6 A The most recent recommendations which I agree</p> <p>7 with involve prolapse above the hymen, and a woman</p> <p>8 who is not symptomatic of bulge or bulge symptoms or</p> <p>9 other symptoms that she had had in association with</p> <p>10 the prolapse.</p> <p>11 Q And are Stage II women, a woman who has been</p> <p>12 staged at Stage II, is that above the hymen?</p> <p>13 A Stage II is defined as women where the</p> <p>14 prolapse exists one centimeter above the hymen,</p> <p>15 zero, which is at the hymen, and one centimeter</p> <p>16 beyond the hymen. So it's that little 2-centimeter</p> <p>17 space that is included in the definition of Stage II</p> <p>18 prolapse.</p> <p>19 Q I'd like to show you the Clinical Study</p> <p>20 Report, I believe, and it's DX257534. Actually,</p> <p>21 that may be the statistical analysis. Ma'am, do you</p> <p>22 recognize that?</p> <p>23 A Yes, I do.</p> <p>24 Q Now you have reviewed a lot of Ethicon's</p> <p>25 records related to the TVM French study report; is</p>



1 (Weber - Cross) Page 142

2 that correct?

3 **A Yes.**

4 Q And do you recognize this as a statistical

5 analysis plan for, I believe this is the five-year

6 data?

7 **A Yes.**

8 Q And how does a statistical analysis plan fit

9 into a clinical trial?

10 **A The statistical analysis plan is the part of**

11 **the protocol that is ordinarily developed before any**

12 **of the data are collected or analyzed, to set out**

13 **how in fact the data are going to be analyzed.**

14 Q I want to refer you to page 11 of that

15 document.

16 **A Yes.**

17 Q Do you recognize this as sample data

18 collection form for follow-up observation?

19 **A Yes.**

20 Q And does this document help the physician when

21 they have a patient, or lady, I mean these are real

22 people that are having these studies, right?

23 **A Yes, they are.**

24 Q And does this document help the physician

25 assess the women when they follow-up for care?

1 (Weber - Cross) Page 143

2 **A Yes.**

3 Q And you would agree with me in this case that

4 Ethicon was collecting information to evaluate the

5 patient at six, 12 months, three years, and five

6 years, correct?

7 **A Yes.**

8 Q And that they were assessing the impact of the

9 prolapse on their sexual activity, correct?

10 **A Yes.**

11 Q They were impacting the prolapse -- or

12 assessing the impact of prolapse on vaginal pain?

13 **A No, not -- that's not what it says.**

14 Q If you look under the vaginal pain section, do

15 you see where they were conducting examinations to

16 determine if an examination provoked dyspareunia,

17 for example?

18 **A I do. If I understood your previous question**

19 **correctly, I thought you had stated directly related**

20 **to the impact of prolapse.**

21 Q This is, and I maybe misspoke and thank you

22 for clarifying that, this is the impact of the

23 treatment, on whether it has caused these problems

24 for the women, in follow-up, correct?

25 **A Yes, that's the intention of this data**

1 (Weber - Cross) Page 144

2 gathering.

3 Q So Ethicon was studying whether their product

4 was going to cause women to have pain with sex,

5 correct?

6 **A That was on this data form. I have not seen**

7 **this on previous data forms that I reviewed.**

8 MS. ROBINSON: Your Honor, move to

9 strike.

10 THE COURT: Was Ethicon studying or

11 not, or you don't know?

12 THE WITNESS: No, not in the case forms

13 that I reviewed.

14 THE COURT: Okay, next question.

15 BY MS. ROBINSON:

16 Q If you look at page 12, you see this is an

17 assessment form for postoperative quality of life;

18 is that correct?

19 **A Yes.**

20 Q And this also is for the TVM French study,

21 which was documented as 2003-016; is that correct?

22 **A Yes.**

23 Q And Ethicon by these forms was collecting

24 information on what impact their product Prolift had

25 on the quality of life of women; is that correct?

1 (Weber - Cross) Page 145

2 **A Yes.**

3 Q And they were assessing such things as whether

4 some of the symptoms that they have interferes with

5 their sexual relationships, correct?

6 **A Yes.**

7 Q They were assessing whether Prolift would

8 affect them so it would interfere with them pursuing

9 new relationships with people, correct?

10 **A The symptoms the woman was experiencing at**

11 **that time would prevent them from pursuing new**

12 **relationships, yes.**

13 Q And also other things, such as how their bowel

14 habits were at the time after having their product,

15 correct?

16 **A Yes.**

17 Q And those are all important things that you

18 want to know about a product that's out there to

19 treat pelvic organ prolapse, correct?

20 **A Yes.**

21 Q I want to go to slide three.

22 Now do you recognize this as the list

23 of women who had failures at 12 months as tallied by

24 Ethicon in its TVM French study?

25 **A Yes.**

(Weber - Cross) Page 146

1

2 Q When you look at this table, you see that each

3 of the women, with the exception of one, were at

4 Stage II, correct?

5 **A Yes.**

6 Q And even though they were at Stage II, they

7 were considered failures; is that correct?

8 **A As defined in the protocol, yes.**

9 Q And only one was a Stage III?

10 **A That's correct.**

11 Q Now you also know that in the study, that

12 Ethicon enrolled women who were at Stage III and IV,

13 correct?

14 **A That was the intention, yes.**

15 Q I want to take a minute and just walk you

16 through one of these patients. Let's look at what

17 information Ethicon collected on Patient 6003. Can

18 you go to DX25019.146.

19 (Pause.)

20 Q So what we have here is Patient 6003, and she

21 was deemed a failure at study, correct? The kind of

22 information Ethicon was collecting, we see at

23 baseline --

24 THE COURT: Whoa, whoa, did you want an

25 answer to that question? Did you answer?

(Weber - Cross) Page 147

1

2 THE WITNESS: No, I didn't.

3 THE COURT: I didn't think you had. Do

4 you want an answer to that question?

5 (No response.)

6 THE COURT: Okay, it's not answered.

7 Next question.

8 MS. ROBINSON: Your Honor, I am going

9 to mark for the witness' benefit D25019.114.

10 Q Ma'am, if you can look at...(Pause.)

11 Ma'am, if you look at page 119 of that

12 document, and that should give you Patient 3006?

13 **A Yes.**

14 Q And you see on there that she has a baseline

15 of POP Q score; is that correct?

16 **A Yes.**

17 Q And baseline just means her condition prior to

18 surgery, correct?

19 **A Yes.**

20 Q And what stage was she before surgery?

21 **A Stage IV.**

22 Q And she had a combined-type surgery, so she

23 had more than just one prolapsed organ, correct?

24 **A I believe what "combined" refers to is**

25 **receiving the total anterior and posterior TVM**

(Weber - Cross) Page 148

1

2 **implant.**

3 Q So she was in an overall stage of IV. Do you

4 see that in the anterior she was at a Stage III, in

5 the posterior she was a Stage III, and a Stage IV in

6 the apical; is that correct?

7 **A Yes.**

8 Q Now after she received treatment, she follows

9 up at six months, and even at six months, at that

10 point she is a Stage II and considered a failure,

11 correct?

12 **A Yes.**

13 Q But if you look across the lines there, does

14 it appear that she is only a failure in one

15 compartment at that point?

16 **A (No response.)**

17 Q You see she is a Stage II in the bladder

18 prolapse section and Stage 0 in the posterior and

19 apical?

20 **A Yes, that is correct. At six months and one**

21 **year and at three years she is a Stage I in the**

22 **apical compartment, and also at five years, while**

23 **she remains a Stage II in the anterior compartment.**

24 Q The one I am looking at has zeros, but

25 notwithstanding that, her prolapse overall doesn't

(Weber - Cross) Page 149

1

2 go down from Stage II throughout the whole entire

3 five-year period that she is studied, correct?

4 **A Yes.**

5 Q Now Ethicon studied her quality of life; is

6 that correct?

7 **A Yes.**

8 Q And can we go to slide four now.

9 I want to approach and hand you

10 D250191.36. Now let's look at Patient 6003's

11 Quality of Life assessment. Now Ethicon assessed

12 these from one to ten, correct?

13 **A I am sorry, can you direct me to what page you**

14 **are on?**

15 Q Page 146. And if you look at Patient 6003, do

16 you see she has Quality of Life scores for one-year

17 and five-year data, correct?

18 **A I am sorry, which column are you looking at?**

19 **Is that the first column? Prolapse affecting life?**

20 Q Yes.

21 **A So that represents a visual analogue scale**

22 **that's not validated.**

23 Q Do you agree that this is a Quality of Life

24 Assessment form?

25 **A Yes, again, just the caveats that we already**

<p>1 (Weber - Cross) Page 150</p> <p>2 mentioned.</p> <p>3 Q Do you agree that this is the table that</p> <p>4 tabulates the information that the woman has</p> <p>5 provided on the Quality of Life Assessment form that</p> <p>6 we showed the jury just a few minutes ago?</p> <p>7 A Some of it, yes.</p> <p>8 Q And as the patient answered those questions</p> <p>9 and was assessed, at one year she was assessed at</p> <p>10 having a quality of life of 9.91, correct?</p> <p>11 A Yes.</p> <p>12 Q And at five years, she remained to have a</p> <p>13 quality of life value of 8.47, correct?</p> <p>14 A That is -- those are the numbers, yes.</p> <p>15 Q And that is on a scale of one to ten?</p> <p>16 A That is correct.</p> <p>17 Q Ma'am, I am handing you Defense Exhibit</p> <p>18 25019.80.</p> <p>19 A I am sorry, could you repeat the number?</p> <p>20 Q 25019.</p> <p>21 A And were there extra digits?</p> <p>22 Q What's the digits in front of you?</p> <p>23 A .54.</p> <p>24 Q Yes, and can you look at Patient 3006 on that</p> <p>25 form?</p>	<p>1 (Weber - Cross) Page 152</p> <p>2 Honor.</p> <p>3 THE COURT: Anything further before we</p> <p>4 recess?</p> <p>5 (A brief recess is taken.)</p> <p>6 THE COURT: Court is back in session,</p> <p>7 please be seated. Do you intend to ask the</p> <p>8 witness about specific portions of these</p> <p>9 articles or just generally about the articles?</p> <p>10 MS. ROBINSON: I have provided to the</p> <p>11 Court articles --</p> <p>12 THE COURT: I am sorry, do you want the</p> <p>13 question read back? Read back the question I</p> <p>14 asked, please.</p> <p>15 MS. ROBINSON: Just generally.</p> <p>16 THE COURT: Fine. Give those documents</p> <p>17 to the witness and let her tell us when we are</p> <p>18 ready, and then bring in the jurors.</p> <p>19 (A further recess is taken.)</p> <p>20 - - -</p> <p>21 (The following transpired at 3:04 p.m.)</p> <p>22 THE COURT: Did you get a chance to</p> <p>23 look at those things?</p> <p>24 THE WITNESS: Yes, I did.</p> <p>25 THE COURT: I am told they are going to</p>
<p>1 (Weber - Cross) Page 151</p> <p>2 A Can you direct me to a page?</p> <p>3 THE COURT: Okay, we are going to take</p> <p>4 a ten-minute recess at this time. Everyone</p> <p>5 please remain seated while the jury leaves the</p> <p>6 courtroom.</p> <p>7 (The jury is excused from the courtroom</p> <p>8 at 2:42 p.m.)</p> <p>9 THE COURT: How many more of these</p> <p>10 documents do you have, Ms. Robinson?</p> <p>11 MS. ROBINSON: Two more.</p> <p>12 THE COURT: And are there any other</p> <p>13 documents that you are going to be using with</p> <p>14 this witness after these two more?</p> <p>15 MS. ROBINSON: Yes.</p> <p>16 THE COURT: How many other documents?</p> <p>17 MS. ROBINSON: Maybe a half dozen. But</p> <p>18 not like these forms.</p> <p>19 THE COURT: You are to give the witness</p> <p>20 all the documents that you intend to use in</p> <p>21 your cross examination, and if there are</p> <p>22 specific lines that you wish the witness to</p> <p>23 look at, like has happened with the last three</p> <p>24 packets, you are to highlight those lines.</p> <p>25 MS. ROBINSON: I will do that, Your</p>	<p>1 (Weber - Cross) Page 153</p> <p>2 ask specific questions about lines on those</p> <p>3 charts and general questions about those</p> <p>4 articles. Are you generally familiar with</p> <p>5 what those articles are?</p> <p>6 THE WITNESS: Yes.</p> <p>7 THE COURT: Okay. Give them to</p> <p>8 counsel.</p> <p>9 (The jury enters the room at 3:05 p.m.)</p> <p>10 THE COURT: Since you just received</p> <p>11 them, counsel, do you need some time to look</p> <p>12 at them?</p> <p>13 MR. SLATER: No, we are fine, Judge.</p> <p>14 THE COURT: Next question.</p> <p>15 BY MS. ROBINSON:</p> <p>16 Q Ma'am, in front of you is Document 25019.60 is</p> <p>17 the page number.</p> <p>18 A Yes.</p> <p>19 Q Now I will pull it up here. This is a chart</p> <p>20 that is analyzing sexual impact; is that correct?</p> <p>21 A That's one of the issues. I am just a little</p> <p>22 worried that the jury may not be seeing this.</p> <p>23 THE COURT: Well, then that's up to</p> <p>24 counsel to worry about. Next question.</p> <p>25 THE WITNESS: Okay.</p>

<p>1 (Weber - Cross) Page 154</p> <p>2 Q So this is a dataset. You are used to</p> <p>3 analyzing these, correct?</p> <p>4 A Yes.</p> <p>5 Q And I want you to look at Patient 3006.</p> <p>6 A Yes.</p> <p>7 Q And cross through there, and it identifies</p> <p>8 that this patient has had no problem with sexual</p> <p>9 activity; is that correct?</p> <p>10 A As baseline, yes.</p> <p>11 Q And throughout the six-month, one-year,</p> <p>12 through three and five years, still remains?</p> <p>13 A It says, "No sex other cause".</p> <p>14 Q So at this point she may not be engaging in</p> <p>15 sexual activity, correct?</p> <p>16 A That's the meaning. She is not. Not that she</p> <p>17 may not.</p> <p>18 Q And the causation is not -- that indicates</p> <p>19 it's not related to the Prolift device, correct?</p> <p>20 A I don't believe that's one of the choices, as</p> <p>21 to whether it's related to the Prolift. She went</p> <p>22 from a baseline of having no limit to her sexual</p> <p>23 activity to being not sexually active after surgery.</p> <p>24 Q And then when it indicates "other cause",</p> <p>25 based on your review of these forms, did you</p>	<p>1 (Weber - Cross) Page 156</p> <p>2 the seven to ten range. Do you see that?</p> <p>3 THE COURT: Do you know what this slide</p> <p>4 is showing?</p> <p>5 THE WITNESS: Yes.</p> <p>6 THE COURT: Do you see whatever it was</p> <p>7 that you were asked if you saw? Ask the</p> <p>8 question again, please. I interrupted.</p> <p>9 Q The patient numbers reflect the patients that</p> <p>10 were deemed failures as a result of the study,</p> <p>11 correct?</p> <p>12 A That Ethicon counted, yes.</p> <p>13 Q And they counted the recurrences, and these</p> <p>14 women had a recurrence, correct?</p> <p>15 A Yes.</p> <p>16 Q And for each of those women where we have</p> <p>17 values thereafter one year, and then again after</p> <p>18 five years, it reflects their level of satisfaction,</p> <p>19 indicating that they were pleased with the operation</p> <p>20 on a level of one to ten, with ten being the</p> <p>21 highest; is that correct?</p> <p>22 A Except for the six women for whom there is no</p> <p>23 information, which is concerning to me, yes.</p> <p>24 Q Now you are referring to the six women that</p> <p>25 you have had added to the failures, correct?</p>
<p>1 (Weber - Cross) Page 155</p> <p>2 understand that that meant that it was a cause</p> <p>3 unrelated to the device?</p> <p>4 A That was not one of the choices.</p> <p>5 THE COURT: Is that your understanding?</p> <p>6 Read back the question.</p> <p>7 (Pending question is read by the court</p> <p>8 reporter.)</p> <p>9 A No.</p> <p>10 Q If you look at the top, do you see that</p> <p>11 Ethicon is also collecting data on vaginal</p> <p>12 retraction?</p> <p>13 A Yes.</p> <p>14 Q And you see that for this lady, each of the</p> <p>15 time points for her follow-up she had no vaginal</p> <p>16 retraction, correct?</p> <p>17 A Yes.</p> <p>18 Q Now I want to show you -- you can set that</p> <p>19 aside. I want to go back and look at slide number</p> <p>20 three, which was all of the failures that Ethicon</p> <p>21 listed for the TVM at 12 months, and I want to take</p> <p>22 a look at the Quality of Life assessments for them,</p> <p>23 and that is going to be slide number five.</p> <p>24 So after one year, where they have</p> <p>25 measurements, most of these women were in at least</p>	<p>1 (Weber - Cross) Page 157</p> <p>2 A No, I am referring to the six women who do not</p> <p>3 have a score on your slide.</p> <p>4 Q Okay, so the six women who don't have a score,</p> <p>5 that's just values that weren't available at the</p> <p>6 one-year time period, correct?</p> <p>7 A No, I believe that means they didn't fill out</p> <p>8 that questionnaire.</p> <p>9 Q Does it also indicate to you that after five</p> <p>10 years all but one also filled out the questionnaire?</p> <p>11 A Yes. Also, the numbers are substantially</p> <p>12 lower.</p> <p>13 Q So you agree with me that the TVM group</p> <p>14 published their results of their one, three, and</p> <p>15 five-year data, correct?</p> <p>16 A No.</p> <p>17 Q You do not agree that Ethicon published their</p> <p>18 one, three, and five-year data?</p> <p>19 A No, I don't believe so.</p> <p>20 Q Do you recall an article by Jacquetin?</p> <p>21 A Could you be more specific?</p> <p>22 Q Do you recall the TVM article by Jacquetin</p> <p>23 that was publishing in the five-year data, correct?</p> <p>24 A Yes.</p> <p>25 Q And is your problem with my question the fact</p>

1 (Weber - Cross) Page 158

2 that you don't believe they published for each of

3 the years that I mentioned?

4 **A Yes.**

5 Q Okay. So you know they published the

6 five-year results?

7 **A The French TVM group, yes.**

8 Q And that's what I am talking about.

9 **A Yes.**

10 Q So the data that we have been looking at here

11 was published by the TVM group after five years,

12 correct?

13 **A Yes.**

14 Q Now you reanalyzed that data, and that's what

15 you presented to the jury here today.

16 THE COURT: That's a statement. Any

17 further questions?

18 Q Did you reanalyze the recurrence rates for the

19 TVM study?

20 **A Not at five years.**

21 Q Did you reanalyze the rates for three years?

22 **A No, I did not.**

23 Q So what was it that you gave to the jury today

24 when you were talking about the failure rates of the

25 TVM study?

1 (Weber - Cross) Page 159

2 **A Perhaps I misspoke. I know for sure that it**

3 **was the one-year for the French and the U.S., and I**

4 **may be mistaken but I don't believe that included**

5 **the three and the five-year results, where I**

6 **analyzed it to the level of the case report forms.**

7 Q You agree with me that your reanalysis,

8 whatever it was, has never been published, right?

9 **A That's right.**

10 Q It's never been peer reviewed, right?

11 **A That's right.**

12 Q No independent person other than you have

13 reviewed that data; is that correct?

14 **A No, that's not correct.**

15 Q And is that another person that was working

16 for Plaintiff's counsel that helped you with the

17 data?

18 **A No. It was not someone who helped me with the**

19 **data.**

20 Q Was it somebody that prepared the data and

21 provided it to you?

22 **A No.**

23 Q Who was it?

24 **A It was someone who performed an independent**

25 **review of the case report forms.**

1 (Weber - Cross) Page 160

2 Q Was she paid for by Plaintiff's counsel?

3 **A Yes.**

4 Q And this data that you analyzed, was that part

5 of what you were paid to do, is that right?

6 **A Yes.**

7 Q And all of the millions of pages that you

8 reviewed, and that's what's got you here so that you

9 are being paid a thousand dollars an hour to

10 testify; is that correct?

11 **A Yes.**

12 Q So the Lucente data that you talked about and

13 reanalyzed, that data came from Dr. Lucente and

14 Dr. Murphy, correct?

15 **A Yes.**

16 Q And it was a spreadsheet that was provided to

17 you; is that also correct?

18 **A Yes.**

19 Q You did not, with that data, you did not go

20 back and look at the actual patient information?

21 **A No. That wasn't available to me.**

22 Q So you were not able to take their spreadsheet

23 and compare it with the individual lady's chart in

24 order to determine whether it was correct or not; is

25 that the case?

1 (Weber - Cross) Page 161

2 MR. SLATER: Your Honor, can we

3 approach sidebar with an objection, Your

4 Honor?

5 THE COURT: Sure.

6 (The following transpired at sidebar:)

7 THE COURT: Yes, what's the objection?

8 MR. SLATER: We were told not to pick

9 up the subpoenas and that's how we got this

10 data. We did everything we could to get the

11 patient level data and couldn't get it through

12 the subpoenas, so it was blocked. So it was

13 not something that would ever possibly be

14 available, it was blocked. So I think it's

15 unfair to ask this witness if it was something

16 she should have looked at if it was legally

17 impossible for us to get it.

18 THE COURT: If they are asking about

19 why she doesn't have it, you can follow up

20 with questions about why she doesn't have it.

21 MR. SLATER: Okay, thank you.

22 THE COURT: But the objection is

23 overruled.

24 MR. SLATER: Fair enough.

25 THE COURT: Judy, read back the last



1 (Weber - Cross) Page 162

2 question.

3 (Pending question is read by the court

4 reporter.)

5 **A Correct, I did not have available to me the**

6 **patient charts.**

7 Q You did have available to you, though, the

8 depositions of Dr. Murphy and Dr. Lucente where they

9 discuss this data; is that correct?

10 **A Yes.**

11 Q And in review of the information that you

12 learned during those depositions, did you come to an

13 understanding that the information on the

14 spreadsheets may be incomplete?

15 **A The information in the deposition testimony**

16 **was contradictory. It was difficult to tell what**

17 **either Dr. Lucente or Dr. Murphy knew about this**

18 **database and what they could tell the lawyers in**

19 **their deposition testimony.**

20 Q And they were not able to verify for you that

21 that was a complete set of the data of the women

22 that they had treated; is that correct?

23 **A I don't believe they were able to verify about**

24 **that, yes.**

25 Q Do you agree with me that data that can't be

1 (Weber - Cross) Page 163

2 verified shouldn't be put out to the medical

3 community?

4 **A That would be a general principle of clinical**

5 **research. And they did anyway.**

6 Q And you took the spreadsheets that they had

7 and you analyzed it as well, correct?

8 **A Yes, that's correct.**

9 Q And in doing that, you learned that a lot of

10 these women had more than one procedure performed at

11 the same time; is that right?

12 **A Yes.**

13 Q And when you listed the information for the

14 jury as to the particular incidences of adverse

15 events that these women had, you did not attempt to

16 relate that one way or the other to the product; is

17 that correct?

18 **A Yes.**

19 Q You also didn't use a protocol when you

20 reviewed those spreadsheets?

21 **A Well, yes, I did.**

22 Q Was that your own protocol?

23 **A I used the protocol of Dr. Lucente to the**

24 **extent possible. It was extremely brief, only four**

25 **pages long, and did not contain the kind of detail**

1 (Weber - Cross) Page 164

2 **that a normal, rigorous sort of protocol for a**

3 **scientific study would include.**

4 Q Based on the information available to you, you

5 did not determine how Dr. Lucente and Dr. Murphy

6 were counting failures, did you?

7 **A In the protocol they defined failure as a**

8 **patient who had a prolapse of Stage II or greater,**

9 **or a patient who required a reoperation for**

10 **prolapse.**

11 Q When you reviewed the data what did you

12 consider as a failure?

13 **A Those two factors, also, in the database**

14 **itself the patient would be declared a failure,**

15 **different terminology was used, support defect, the**

16 **fact that she had had a reoperation despite being**

17 **characterized as a success in the final column.**

18 **If I had my summary report of my**

19 **analysis of that database I could be sure that**

20 **definition was as complete as it could be. That's**

21 **the main factors that I remember right now.**

22 Q But your definition was different than the

23 protocol?

24 **A My definition was drawn from the protocol and**

25 **words in the spreadsheet that unequivocally assigned**

1 (Weber - Cross) Page 165

2 **a woman to a category of failure.**

3 Q Based on your opinion?

4 **A No, it's not my opinion. If someone writes**

5 **"support defect" in the spreadsheet, that in medical**

6 **terminology, in research terminology, that is a**

7 **failure.**

8 Q Do you have any sense as to whether the study,

9 Murphy and Lucente study was counting failures in

10 treated compartments only?

11 **A I would have to look back at the protocol to**

12 **be sure. I counted it both ways, to have both**

13 **numbers accessible.**

14 Q When you assessed Lucente's and Murphy's

15 spreadsheet you counted failures as if it would be

16 in either compartment would count as a failure,

17 right?

18 **A If they declared it was a failure, I counted**

19 **it as a failure.**

20 Q And when you did your own study back in 2001,

21 you only counted failures when they were in the

22 treated compartment; is that correct?

23 **A That was the endpoint of that randomized**

24 **trial, yes, one of the endpoints.**

25 Q Now you would agree with me that when you

1 (Weber - Cross) Page 166

2 looked at the TVM data for the exposure rates, that

3 you calculated the exposure rates based on whether

4 the mesh was palpable, correct?

5 **A Yes.**

6 Q And whether it was visible and palpable,

7 correct?

8 **A Yes.**

9 Q And if it was just visible. Is that right?

10 **A Yes.**

11 Q And you counted all of those; is that correct?

12 **A Yes, as defined in the protocol.**

13 Q What does palpable mean?

14 **A Palpable means that the doctor can feel the**

15 **mesh erosion, the pull, if you will, in the vaginal**

16 **wall with the examining hand or fingers.**

17 Q Palpable is still under the skin, right?

18 **A No.**

19 Q When you feel something that's palpable, has

20 it come through the skin?

21 **A Yes.**

22 Q A palpable mesh has come through the skin?

23 **A A palpable mesh erosion has come through the**

24 **skin.**

25 Q And that's your definition?

1 (Weber - Cross) Page 167

2 **A Yes.**

3 Q When you were defining erosion before, I think

4 you called it as something that was eating away

5 through the lining and could be seen in the vagina?

6 **A Yes.**

7 Q So how is palpable and visible different?

8 **A Palpable, the reason a doctor may only be able**

9 **to palpate a mesh erosion and not at the same time**

10 **be able to see it is depending on the contour of the**

11 **vagina itself. The normal vagina has folds and**

12 **rugae, that's the term for those little ups and**

13 **downs on the vaginal wall. Also, after the mesh**

14 **implantation there may be vaginal anatomic**

15 **distortion, so that it's not possible to see clearly**

16 **into all of the areas of the vagina. So the doctor**

17 **can palpate it with his finger, but he just can't**

18 **arrange his instruments, the speculum, the woman may**

19 **be very uncomfortable during the examination and he**

20 **doesn't want to make it worse for her, so he may**

21 **just not be able to actually make it visible at the**

22 **same time that he is able to palpate.**

23 Q Ma'am, I think that your attorney gave you a

24 Clinical Study Report earlier as an exhibit for the

25 French data, correct? Do you have the Clinical

1 (Weber - Cross) Page 168

2 Study Report in front of you?

3 THE COURT: Do you have a copy you can

4 pass up?

5 THE WITNESS: I do have it, Your Honor.

6 THE COURT: Okay, great.

7 MS. ROBINSON: It's page 49. It's

8 actually 48 and 49, where it discusses the TVM

9 mesh exposure.

10 Q On page 49, do you see up at the top, do you

11 have an understanding as to whether the TVM doctors

12 considered a mesh that was palpable to be a mesh

13 exposure?

14 **A I see what you are referring to. That's not**

15 **generally how it's understood in the medical**

16 **community.**

17 Q So, ma'am, is it the case that some of the

18 women that you assess as having mesh exposure had

19 palpable exposure rather than, as these doctors have

20 indicated it should be counted where it's either

21 visible or visible and palpable?

22 **A That's possible.**

23 Q So you have a list of women that you have

24 added to the failure, to the mesh exposure group,

25 right, and those women basically have palpable mesh,

1 (Weber - Cross) Page 169

2 correct?

3 **A No.**

4 Q You have in front of you Defense Exhibit

5 25019?

6 **A Okay.**

7 Q And I would like you to turn to page 11 -- I

8 am sorry, 109 and 110.

9 **A Okay.**

10 Q And I have highlighted for you --

11 **A Yes.**

12 Q Patients Number 7006 and 7010. Were those

13 patients that you added to the failures that Ethicon

14 had?

15 **A I would need to see my list of the mesh**

16 **exposures.**

17 Q I am going to hand you, just for purposes to

18 see if it refreshes your memory, my copy of your

19 list.

20 THE COURT: Read the exhibit number for

21 the record, Charles.

22 THE COURT CRIER: It says Weber 15.

23 Weber 15, Your Honor.

24 THE COURT: Give it to the witness.

25 Q Do you recognize that as an exhibit that you

1 (Weber - Cross) Page 170

2 would have seen during your deposition in August of

3 this year?

4 **A Yes.**

5 Q And on the back page does it list the patients

6 that you counted as having mesh exposures?

7 **A Yes.**

8 Q And is Patient 7006 on that list?

9 **A Yes.**

10 Q As well as Patient 7010?

11 **A Yes.**

12 Q And I will refer you back and we will show the

13 jury DX25019, page 109.

14 Do you see that Patient 7006, at six

15 months and one year only had palpable mesh?

16 **A Yes.**

17 Q And you see that at three years and five

18 years, without treatment, neither one of those

19 patients had any palpable mesh?

20 **A Yes.**

21 Q Now that's a patient that you counted,

22 correct?

23 **A Yes.**

24 Q Now you reanalyzed your own data, didn't you,

25 your own data from your 2001 Study that showed

1 (Weber - Cross) Page 171

2 failure rates in the anterior colporrhaphy repair

3 range from 54 percent to 70 percent, you reanalyzed

4 that data; is that correct?

5 **A Yes.**

6 Q And you did that in 2011?

7 **A The Study was published in 2011, yes.**

8 Q When you published the Study, those rates went

9 way down; is that correct?

10 **A Yes.**

11 Q And you found that many more women had

12 successes from the anterior colporrhaphys than you

13 had originally published, correct?

14 **A Yes. It was a different definition.**

15 Q Now when you published this in 2011, did you

16 disclose that you had been working with Mr. Slater?

17 **A No.**

18 Q You didn't think the medical community needed

19 to know that you were working for an attorney

20 representing women who had complaints having to do

21 with Prolift?

22 **A No.**

23 Q You didn't think that was important?

24 **A That is not a standard in medical publishing.**

25 Q Earlier today you testified about the ACOG

1 (Weber - Cross) Page 172

2 manual? Do you have a copy of it up there?

3 **A The Practice Bulletin?**

4 Q Yes, the Practice Bulletin.

5 **A Yes.**

6 Q And I am going to show you the language that

7 you referred to that was removed from the Practice

8 Bulletin, and that language was whether this was an

9 experimental procedure, correct?

10 **A Yes.**

11 Q When it was republished in September of 2007,

12 do you agree with me that the only words changed or

13 removed from that publication were the ones that are

14 highlighted there?

15 **A Yes.**

16 Q So everything else in that whole entire

17 Practice Bulletin is exactly the same, right?

18 **A Yes.**

19 Q No one changed anything about what you said

20 about Prolift or mesh kits in that Bulletin,

21 correct?

22 **A Except --**

23 Q Except for the "experimental"?

24 **A Right.**

25 Q You had other information in that Bulletin

1 (Weber - Cross) Page 173

2 about the outcomes related to the mesh kits,

3 correct?

4 **A Yes.**

5 Q And nobody took that out, right?

6 **A That's right.**

7 Q You also were asked about a letter that you

8 wrote after this change had happened; is that

9 correct?

10 **A After the publication of the article of Drs.**

11 **Wall and Brown, yes.**

12 Q And this is what you had to say about that,

13 right?

14 Do you agree with me that before the

15 change was made in September of 2007, that it

16 underwent the exact same review as it did the first

17 time it was published?

18 **A I think you are mistakenly representing what**

19 **is on the screen at the moment.**

20 THE COURT: Well, let's start with is

21 that what you want on the screen?

22 MS. ROBINSON: No, we can take the

23 screen off --

24 THE COURT: Take the screen down. Do

25 you want the question read back or stated

(Weber - Cross) Page 174

1 again.

2 THE WITNESS: Yes.

3 (The question is read by the court

4 reporter.)

5 **A That's what ACOG said. That's not what I was**

6 **told by people who attended that meeting.**

7 THE COURT: So would you agree with

8 counsel or not?

9 THE WITNESS: No, I don't agree.

10 Q So let's talk a minute about dyspareunia or

11 pain with sex. Do you agree with me that there are

12 many factors that can cause dyspareunia?

13 **A Yes.**

14 Q Do you agree that eight to 13 percent of

15 middle-age women can have sexual dysfunction?

16 **A If you are referring to a specific document,**

17 **that may help.**

18 Q If you want to look in front of you.

19 MS. ROBINSON: I am going to apologize

20 to the Court because I wasn't planning on

21 using this document.

22 THE COURT: It's okay.

23 Q I am going to hand you Exhibit D32265. I will

24 ask you to look at that and see if it refreshes your

25

(Weber - Cross) Page 175

1 memory about an article that you wrote back in 2000?

2 **A Yes. Perhaps I misheard the question. But I**

3 **see what you are referring to, yes.**

4 Q Okay, and my question again is do you agree

5 that there is a high prevalence of sexual

6 dysfunction in middle-aged and elderly women in the

7 community, including dyspareunia, which ranges

8 between eight to 13 percent?

9 **A Yes.**

10 Q Do you agree that there are many factors that

11 can have a woman to have high occurrence of

12 dyspareunia including menopause?

13 **A That's a possibility, yes.**

14 Q Vaginal dryness or atrophy?

15 **A Yes.**

16 Q Symptomatic pelvic organ prolapse?

17 **A Yes.**

18 Q Prior vaginal surgeries?

19 **A Yes.**

20 Q Including a total vaginal hysterectomy?

21 **A Possibly, yes.**

22 Q Anterior colporrhaphy?

23 **A Yes.**

24 Q Posterior colporrhaphy?

25

(Weber - Cross) Page 176

1 **A Yes.**

2 Q In fact, would you agree with me that

3 posterior colporrhaphy can have a range of

4 dyspareunia that can equal close to 26 percent?

5 **A Yes.**

6 Q You have also found, have you not, that the

7 normal vaginal length for a woman has been reported

8 to be between seven and 11 centimeters, correct?

9 **A Average. Average may not be exactly the same**

10 **as normal.**

11 Q So when you are a doctor and you are trying to

12 determine what you consider to be a woman's normal

13 vaginal length, what term do you use, average or

14 normal?

15 **A I mean the words have different meanings. I**

16 **guess I don't understand your context.**

17 Q Well, I am trying to figure out what the

18 difference is between average and normal as you have

19 just stated?

20 **A Well, that's what I stated in this article,**

21 **where we were endeavoring to describe vaginal**

22 **dimensions that would be favorable to achieve at the**

23 **time of reconstructive vaginal surgery for prolapse.**

24 **So the average posterior vaginal length has been**

25

(Weber - Cross) Page 177

1 **reported from seven to 11 centimeters.**

2 Q Now the study you did here in 2000 involved

3 women undergoing repair for a posterior repair,

4 correct?

5 **A That was one of the procedures that was**

6 **performed, yes.**

7 Q And in your study did you determine that

8 19 percent of the women after undergoing the surgery

9 had dyspareunia?

10 **A Yes.**

11 Q You stated, in fact, that posterior

12 colporrhaphy is significantly associated with

13 dyspareunia?

14 **A Yes.**

15 Q What does that mean "significantly

16 associated"? Is that a statistical term?

17 **A Yes, I believe so, in that situation. Yes.**

18 Q I want to ask you just a couple of last

19 questions. Is it true that there are more

20 randomized control trials for Gynemesh PS than any

21 other product for pelvic organ prolapse?

22 **A Yes.**

23 Q Is it also true that there are more randomized

24 controlled trials for the Prolift kit than any other

25

<p>1 <b>(Weber - Redirect)</b> Page 178</p> <p>2 mesh kits out there for pelvic organ prolapse?</p> <p>3 <b>A Yes.</b></p> <p>4 MS. ROBINSON: Thank you.</p> <p>5 THE COURT: Mr. Slater, is there any</p> <p>6 redirect?</p> <p>7 MR. SLATER: A little bit, Your Honor.</p> <p>8 - - -</p> <p>9 REDIRECT EXAMINATION</p> <p>10 - - -</p> <p>11 BY MR. SLATER:</p> <p>12 Q Doctor Weber, let's go over a couple of quick</p> <p>13 things. I will try to be brief. We have some other</p> <p>14 stuff to do.</p> <p>15 You testified to the fee that you are</p> <p>16 charging for today's testimony?</p> <p>17 <b>A Yes.</b></p> <p>18 Q When you are not in court what's the hourly</p> <p>19 rate that you charge?</p> <p>20 <b>A \$350 an hour.</b></p> <p>21 Q The numbers that you charge to my law firm,</p> <p>22 did you pull that out of the air, where did you come</p> <p>23 up with those?</p> <p>24 <b>A No. When we first spoke about the possibility</b></p> <p>25 <b>of working together, I asked some of my</b></p>	<p>1 <b>(Weber - Redirect)</b> Page 180</p> <p>2 <b>A Yes.</b></p> <p>3 Q The article that you published in 2001, that</p> <p>4 was not just you, you had coauthors, right?</p> <p>5 <b>A Yes.</b></p> <p>6 Q Tell the jury about some of your coauthors,</p> <p>7 who else published that article with you?</p> <p>8 <b>A So in 2001, which was the randomized trial of</b></p> <p>9 <b>the three different anterior repair techniques, my</b></p> <p>10 <b>coauthors were my partners in our practice at the</b></p> <p>11 <b>Cleveland Clinic. Mark Walters, who had served as</b></p> <p>12 <b>an officer in the professional organizations that we</b></p> <p>13 <b>have been talking about, the American Urogynecology</b></p> <p>14 <b>Society and so on, and then a couple of my senior</b></p> <p>15 <b>partners who had been doing prolapse surgery for</b></p> <p>16 <b>decades, and a statistician.</b></p> <p>17 Q Now, the 2011 article, who were your coauthors</p> <p>18 on that article?</p> <p>19 <b>A So that included the original surgeons if they</b></p> <p>20 <b>were still at the clinic, a couple -- my senior</b></p> <p>21 <b>colleagues had retired by that time.</b></p> <p>22 <b>Dr. Chimelewski, who is the lead author on that</b></p> <p>23 <b>article, was a fellow at the Clinic at that time so</b></p> <p>24 <b>she was in the advanced training that</b></p> <p>25 <b>urogynecologists get. Dr. Matt Barber, who is a</b></p>
<p>1 <b>(Weber - Redirect)</b> Page 179</p> <p>2 <b>colleagues -- I hadn't done this kind of work</b></p> <p>3 <b>before -- what was considered reasonable and</b></p> <p>4 <b>customary.</b></p> <p>5 MS. ROBINSON: Objection.</p> <p>6 THE COURT: Overruled.</p> <p>7 <b>A And you and I also discussed what was</b></p> <p>8 <b>reasonable and customary in your experience, and</b></p> <p>9 <b>that is how we settled on that figure.</b></p> <p>10 Q Now the opinions that you put into that letter</p> <p>11 about what those people on ACOG did in changing your</p> <p>12 Bulletin and the strong statement you made to the</p> <p>13 public, did you make those statements and form those</p> <p>14 opinions before or after you ever spoke to me?</p> <p>15 <b>A Before.</b></p> <p>16 Q You were asked about being Board certified in</p> <p>17 female pelvic reconstructive surgery. Is that a</p> <p>18 Board certification that existed when you were</p> <p>19 treating patients?</p> <p>20 <b>A No. It only just came this year.</b></p> <p>21 Q You were asked if you had witnessed pelvic</p> <p>22 surgery. Have you witnessed videos of actual</p> <p>23 surgeons performing Prolift surgery?</p> <p>24 <b>A Yes.</b></p> <p>25 Q Have you seen more than one of those?</p>	<p>1 <b>(Weber - Redirect)</b> Page 181</p> <p>2 <b>staff member at the Cleveland Clinic, also, he had</b></p> <p>3 <b>just recently finished serving as president for the</b></p> <p>4 <b>American Urogynecologic Society.</b></p> <p>5 Q So the decision to reevaluate those</p> <p>6 statistics, was that your decision alone?</p> <p>7 <b>A No.</b></p> <p>8 Q The former president of AUGS was also one of</p> <p>9 the people?</p> <p>10 <b>A Yes. It was actually his idea, and then we</b></p> <p>11 <b>all worked on the analysis together.</b></p> <p>12 Q Now you were just asked about an article from</p> <p>13 2000 about dyspareunia rates with posterior repairs.</p> <p>14 Do you remember that?</p> <p>15 <b>A Yes.</b></p> <p>16 Q Is there a little more information to that,</p> <p>17 about the prevalence and which patients had that and</p> <p>18 the types of procedures being done that you could</p> <p>19 share with the jury please?</p> <p>20 <b>A I am sorry?</b></p> <p>21 Q That you could share with the jury, please?</p> <p>22 <b>A Oh, yes. So this article about sexual</b></p> <p>23 <b>function described women who were undergoing a</b></p> <p>24 <b>number of different procedures, because prolapse</b></p> <p>25 <b>very rarely occurs in one part of the vagina.</b></p>



<p>1 <b>(Weber - Redirect)</b> Page 182</p> <p>2 Remember we talked about the compartments and how we</p> <p>3 artificially separate that out. But that's not</p> <p>4 really how the body functions, so it's very common</p> <p>5 for more than one aspect of the vagina to be</p> <p>6 affected at the same time, and also to have</p> <p>7 incontinence and possibly some bowel issues. So</p> <p>8 this was surgery to care for all the women's</p> <p>9 problems at once, and so they had a combination of</p> <p>10 procedures to help take care of that, and then we</p> <p>11 followed them over time and assessed their sexual</p> <p>12 function.</p> <p>13 Q Okay, now, doctor, you were also asked about</p> <p>14 another article that -- it would be the first</p> <p>15 article, if you have that PLT -- actually, they gave</p> <p>16 you the defense exhibit, but it's the 2001</p> <p>17 randomized control article?</p> <p>18 A Okay, go ahead.</p> <p>19 Q You were asked about the recurrence rates. In</p> <p>20 terms of whether or not anterior colporrhaphy, the</p> <p>21 suture procedure to treat bladder prolapse, in terms</p> <p>22 of whether or not that provides relief of symptoms</p> <p>23 and a good functional result, what did you conclude</p> <p>24 in that article?</p> <p>25 A Yes. The women had a very good functional</p>	<p>1 <b>(Weber - Redirect)</b> Page 184</p> <p>2 injury to the bladder because of the way the mesh is</p> <p>3 embedded in the tissues and the way the bladder wall</p> <p>4 grows into the mesh, just like on the other side the</p> <p>5 vaginal wall grows into the mesh, and I am speaking</p> <p>6 specifically the anterior here but the same thing</p> <p>7 happens posteriorly. So if the surgeon has to try</p> <p>8 to remove mesh, then there is a high likelihood of</p> <p>9 creating damage in the bladder in trying to get the</p> <p>10 mesh out of the bladder wall.</p> <p>11 Q Now you were asked about the person who also</p> <p>12 reviewed the data from the Gynemesh PS study and the</p> <p>13 TVM study, remember Ms. Robinson asked you some</p> <p>14 questions about that person?</p> <p>15 A Yes.</p> <p>16 Q Just so we understand, who was that person?</p> <p>17 A That was Dr. Susan Shot. She is a biomedical</p> <p>18 statistician, and this is what she does for her</p> <p>19 livelihood.</p> <p>20 Q In fact, on that Iglesia article I gave you,</p> <p>21 the one that talked about the 15 percent stopping</p> <p>22 point, was she involved with that study?</p> <p>23 A Yes, she was the statistician of record and a</p> <p>24 co-author on the publication.</p> <p>25 Q We heard about the IIS study, that studied</p>
<p>1 <b>(Weber - Redirect)</b> Page 183</p> <p>2 result, which means their symptoms improved greatly</p> <p>3 after the surgery, and they didn't experience new</p> <p>4 complications or severe problems. In this group of</p> <p>5 women no one needed a reoperation for prolapse, and</p> <p>6 there were no reoperations or complications.</p> <p>7 Q Now going with that, if a woman has a</p> <p>8 recurrence and needs to have something done after a</p> <p>9 suture repair, as opposed to a reoperation due to a</p> <p>10 mesh-related complication, are we looking at the</p> <p>11 same thing or something different?</p> <p>12 A No, those are two totally different</p> <p>13 categories.</p> <p>14 Q Very simply, why?</p> <p>15 A A reoperation for prolapse, after a woman has</p> <p>16 had a suture procedure, she still has open to her</p> <p>17 any of the other alternatives. It doesn't preclude</p> <p>18 her from having any of the other different kinds of</p> <p>19 operations. If a woman is having a reoperation for</p> <p>20 a mesh complication, that's a very different and</p> <p>21 serious matter, that if her complication is so</p> <p>22 severe as to require surgery, there is a high level</p> <p>23 of possible morbidity to the nearby organs, and</p> <p>24 morbidity just means more complications. The</p> <p>25 bladder is right nearby, it's very common to have an</p>	<p>1 <b>(Weber - Redirect)</b> Page 185</p> <p>2 Dr. Lucente's data?</p> <p>3 A Yes.</p> <p>4 Q First of all, pursuant to the agreement</p> <p>5 between Dr. Lucente and Ethicon, did Ethicon have</p> <p>6 the ability to obtain and review that data?</p> <p>7 A Yes.</p> <p>8 Q And you were asked a question about deposition</p> <p>9 testimony of Dr. Lucente, and I just want to -- if I</p> <p>10 could just hand this up, please.</p> <p>11 Doctor, what I would like to do is draw</p> <p>12 your attention to specific testimony. You relied on</p> <p>13 these depositions?</p> <p>14 A Yes.</p> <p>15 Q You were asked about them on cross</p> <p>16 examination?</p> <p>17 A Yes.</p> <p>18 Q If you could turn to page 33, please. You</p> <p>19 were asked questions about whether you had the</p> <p>20 complete data?</p> <p>21 A Yes.</p> <p>22 Q Page 33, line eight, the question of</p> <p>23 Dr. Lucente, which was in his deposition of June 10,</p> <p>24 2014, "The data that was produced for the Prolift</p> <p>25 database and the TVT secure study that were funded</p>

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2 by Ethicon that are identified in this letter, where

3 we provided all the data in existence with regard to

4 those two studies?"

5 His Answer: "That's my understanding,

6 yes.

7 "Q And you confirmed that before it was

8 produced to us?

9 "A Yes."

10 Did you rely on that testimony from

11 Dr. Lucente?

12 A Yes, I did.

13 Q And if you could turn, please, to Page 111,

14 line 9, question of Dr. Lucente:

15 "Q To your knowledge, there are no other

16 databases that encompass patients within this

17 Prolift study, otherwise you would have

18 produced it to us, correct?"

19 And Dr. Lucente said, Yes. Correct?

20 A Yes.

21 Q Based on that testimony, do you feel

22 comfortable that you saw all of the data that

23 Dr. Lucente had on that study?

24 A Yes.

25 MR. SLATER: No further questions, Your

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2 Honor.

3 THE COURT: Is there anything further?

4 MS. ROBINSON: No, Your Honor.

5 THE COURT: Thank you. Ladies and

6 gentlemen, we are going to take a brief recess

7 and see what's next, and then after the jury

8 leaves the courtroom you can step down. Thank

9 you.

10 (The jury is excused.)

11 - - -

12 (The witness is excused.)

13 - - -

14 THE COURT: Who is your next witness?

15 MR. SPECTER: Your Honor, we have two

16 brief videos to show, they are 20 minutes in

17 length total, and then we have Dr. Zipper.

18 THE COURT: Which are these two videos?

19 MR. SPECTER: St. Hilaire, and

20 Dr. Lucente.

21 THE COURT: Any objections that have to

22 be ruled on?

23 MS. ISMAIL: I don't believe so, Your

24 Honor. The one issue, for the record, in

25 Chambers you had asked us if there is a, if I

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2 can paraphrase, rule of proportionality as to

3 our counters, we have extensive counter

4 designation. That's true for Dr. Lucente. We

5 have agreed with Plaintiff's counsel that we

6 will hold that examination for our case in

7 chief if we so choose. There was a very short

8 counter that we had proposed to the subject

9 matter that the Plaintiffs wanted to play, it

10 looks like we are not going to be able to work

11 that out technically, that we don't have the

12 ability to play your -- there was a couple of

13 questions that we wanted to ask on the

14 compensation issue, which is what counsel is

15 playing the deposition for. If we could play

16 that in completeness, there is a one-minute

17 designation, and then reserve for the balance

18 of our examination for our case in chief is

19 what we are asking.

20 MR. SLATER: We had a written agreement

21 last week on what we were going to play. They

22 asked us today, we couldn't cut it, we don't

23 want to now change the video, we have a

24 written agreement.

25 THE COURT: Fine, you can read it to

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2 the jury after the video is finished.

3 MS. ISMAIL: We will talk over the

4 break.

5 THE COURT: If you wish not to read it

6 to the jury after the video is finished, you

7 won't read it to the jury after the video is

8 finished.

9 MS. ISMAIL: Yes, Your Honor.

10 THE COURT: What else? How about after

11 this 20 minutes? Dr. Zipper is here and

12 available?

13 MR. SPECTER: Yes, he is.

14 THE COURT: Well, then maybe we can at

15 least get the credentials out of the way for

16 Dr. Zipper.

17 Do you have any motions for Dr. Zipper?

18 MS. ISMAIL: Your Honor, we did have a

19 motion for Dr. Zipper. There was one issue on

20 qualifications I expect isn't going to be the

21 subject of his testimony and he is going to be

22 called only on --

23 MR. SPECTER: Yes, that's true.

24 MS. ISMAIL: No, no, that's not -- my

25 question was going to be on that he is really

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1 being called on case-specific bases. We had a  
2 question on qualifications to any opinions the  
3 witness intends to offer on biomaterials,  
4 which is a scientific specialty that this  
5 witness is not qualified.  
6  
7 THE COURT: Are you going to present  
8 any opinion testimony on biomaterials?  
9  
10 MR. SPECTER: Your Honor, Dr. Zipper is  
11 being proffered as an expert in urogynecology, in  
12 pelvic floor reconstructive surgery, in  
13 vaginal mesh materials, and in the Prolift.  
14 Depending upon how one defines the term  
15 "biomaterials," I am not quite sure how  
16 counsel is thinking about that term, there  
17 could be an overlap with vaginal mesh  
18 materials, I am not sure. I am not sure what  
19 he is thinking about.  
20  
21 THE COURT: Okay. So where are we?  
22  
23 MS. ISMAIL: I am not sure how to  
24 interpret counsel's answer.  
25  
26 THE COURT: Okay, he is asking what you  
27 mean by biomaterial testimony. Are you able  
28 to define it?  
29  
30 MS. ISMAIL: Yes, so the --

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1 THE COURT: Does his report say  
2 anything about biomaterials?  
3  
4 MS. ISMAIL: It does in part, Your  
5 Honor.  
6  
7 THE COURT: Show Mr. Specter the part  
8 that it talks about biomaterials. And in the  
9 event, Mr. Specter, you are going to cover any  
10 of that on direct, and you can see me in  
11 chambers on the record.  
12  
13 MS. ISMAIL: Thank you, Your Honor.  
14 (A brief recess is taken.)  
15  
16  
17 (The following transpired in the robing  
18 room with counsel present:)  
19  
20 MS. ISMAIL: Your Honor, I conferred  
21 with Mr. Specter and Mr. Specter indicated as  
22 to one of our objections that Dr. Zipper will  
23 not opine as to degradation of polypropylene  
24 mesh, which was one of our concerns, so that's  
25 off the table. My question to him is whether  
26 he intends to have this witness describe the  
27 properties of polypropylene and its effect on  
28 the body. I understood from Mr. Specter  
29 that's not going to be the focus of his

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1 examination and that if I have particular  
2 objections to questions that exceed  
3 Dr. Zipper's qualifications I should raise  
4 them. I wanted to make sure that was okay  
5 with the Court if I stood up and asked for a  
6 sidebar --  
7  
8 THE COURT: I would prefer that you  
9 stand up and object and then ask for a  
10 sidebar.  
11  
12 What is the area that you think might  
13 be objectionable? You said it a minute ago?  
14  
15 MS. ISMAIL: The effect of  
16 polypropylene.  
17  
18 THE COURT: The effect of polypropylene  
19 in the Prolift?  
20  
21 MS. ISMAIL: In the Prolift, which  
22 would require him to opine as to the effect of  
23 that material in the human body, which we  
24 believe --  
25  
26 THE COURT: Do you expect the testimony  
27 to go into the area of the effect of the  
28 polypropylene which is what the Prolift is  
29 made of in the body?  
30  
31 MR. SPECTER: Sure.

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1 THE COURT: So when it exceeds his  
2 qualifications you should at that point object  
3 and we will be able to deal with it.  
4  
5 MS. ISMAIL: Very well, Your Honor.  
6  
7 THE COURT: Is that it?  
8  
9 MR. SPECTER: Yes.  
10  
11 THE COURT: Perfect, thank you. Tell  
12 Charles to bring in the jury. Are we ready  
13 with the video, whatever is next?  
14  
15 MR. SPECTER: Yes.  
16  
17 (The following transpired in open  
18 court:)  
19  
20 THE COURT: Call your next witness.  
21  
22 MR. SPECTER: Thank you, Your Honor.  
23  
24 Your Honor, at this time, as we advised the  
25 Court, we have two brief videos for the jury  
26 to see, a total of 20 minutes. The first is  
27 Price St. Hilaire, who is an Ethicon employee.  
28 The second is Dr. Lucente, who we heard about  
29 earlier today.  
30  
31 (At this time, the designated portion  
32 of the videotaped deposition testimony of  
33 Price St. Hilaire is played for the jury.)  
34  
35 THE COURT: Next witness.

1 **(Hammons v Ethicon, et al.)** Page 194  
2 MR. SPECTER: Dr. Lucente, Your Honor.  
3 (At this time, the designated portion  
4 of the videotaped deposition testimony of  
5 Vincent Lucente, MD, is played for the jury.)  
6 THE COURT: Ladies and gentlemen of the  
7 jury, we are going to break at this time. I  
8 will ask you to return at 9:30 tomorrow  
9 morning. Between now and when you return,  
10 keep an open mind and don't discuss the case  
11 with anyone, including everything one at home.  
12 Charles?  
13 (The jury exits the courtroom at 4:35  
14 p.m., and the following transpired in open  
15 court:)  
16 THE COURT: Plaintiff, your next  
17 witness is Dr. Zipper?  
18 MR. SPECTER: Yes, sir.  
19 THE COURT: And then who?  
20 MR. SPECTER: We are going to have some  
21 more video, Your Honor.  
22 THE COURT: Can you tell me who?  
23 MR. SPECTER: If I may consult with  
24 Mr. Slater, yes.  
25 THE COURT: Yes.

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2 MR. SLATER: We have Piet Hinoul; Aaron  
3 Kirkemo; Charlotte Owens.  
4 THE COURT: Go ahead.  
5 MR. SLATER: Jim Hart; Kimberly  
6 Hunsicker; Scott Jones; Bryan Lisa; Paul  
7 Parisi; and along with Dr. Zipper, that is  
8 certainly more than enough to cover tomorrow.  
9 THE COURT: Okay. Who was asking about  
10 Mr. Parisi?  
11 MR. SLATER: Subject to the order in  
12 which we play them, we have Dr. Baker, Dr.  
13 Klinge, we have Renee Selman, Sheri McCoy,  
14 Alex Gorsky, Axel Arnaud -- he will be earlier  
15 than last, though, he will not be the last  
16 one.  
17 THE COURT: Okay. Who else?  
18 MR. SLATER: David Robinson. We  
19 believe that's it, Your Honor.  
20 THE COURT: That's all your case?  
21 MR. SLATER: And Mrs. Hammons.  
22 THE COURT: Are there objections on any  
23 of these videos?  
24 MS. ISMAIL: Your Honor, we raised for  
25 the Court's attention already the Kirkemo and

1 **(Hammons v Ethicon, et al.)** Page 196  
2 the Hinoul issue.  
3 THE COURT: Yes, Kirkemo and?  
4 MS. ISMAIL: Hinoul, same issue.  
5 THE COURT: Are there any other issues  
6 besides that one? Any other objections that  
7 need a ruling on any of these?  
8 MS. ISMAIL: Potentially.  
9 THE COURT: Fair enough.  
10 MS. ISMAIL: Selman, McCoy and Gorsky,  
11 but I will look at them again tonight and we  
12 will advise the Court.  
13 THE COURT: But that's it? They just  
14 haven't been worked out or withdrawn, is that  
15 right?  
16 MS. ISMAIL: Yes, Your Honor.  
17 THE COURT: So I am ready to deal with  
18 the totality of Kirkemo's deposition and the  
19 first questioning of Hinoul's deposition. I  
20 will hear from you.  
21 MR. MORIARTY: So, Your Honor, on  
22 Kirkemo, it's a designation of approximately  
23 four minutes. The sole purpose of this is to  
24 get right to the off-color E-mail. There is  
25 really no substantive questioning at all, no

1 **(Hammons v Ethicon, et al.)** Page 197  
2 registry, it's not an issue in the case at  
3 all, it's not covered with other witnesses.  
4 We filed Motion in Limine Number nine to  
5 preclude things just like off-color E-mails,  
6 that was specifically discussed.  
7 THE COURT: That was denied, wasn't it?  
8 MR. MORIARTY: It was denied because --  
9 THE COURT: So why don't we just deal  
10 with this.  
11 MR. MORIARTY: This E-mail is four  
12 years after the product launch, and it is  
13 irrelevant under 402, and it is highly  
14 prejudicial under 403.  
15 THE COURT: Plaintiff? Do you wish to  
16 be heard?  
17 MR. SLATER: Yes, Your Honor. The  
18 testimony around that E-mail by Dr. Kirkemo  
19 and Dr. Hinoul directly relates to our  
20 punitive damage claims. Under New Jersey law,  
21 we have to prove wanton and willful disregard  
22 of the rights, the health, the condition of  
23 plaintiff, and in this E-mail we see two of  
24 the Medical Affairs directors at Ethicon  
25 making jokes about mesh-injured women, which

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2 as doctors, especially as medical directors,  
3 would be the last thing that anybody would  
4 expect them to be doing.  
5 It goes directly to the heart of our  
6 punitive claim. And the defense calls them  
7 off-color E-mails, I don't know what that  
8 means. I know that this is a couple of  
9 medical directors making jokes about  
10 mesh-injured women, to the point to where  
11 Kirkemo actually does a POP-Q calculation of  
12 how a woman's vagina would have to be shaped  
13 so you could fit a floppy disk into it.  
14 Is it prejudicial to them? Absolutely.  
15 It's not unduly prejudicial, and again, it  
16 goes directly to the heart of our punitive  
17 claims which we need to prove.  
18 THE COURT: I am sorry to hear it goes  
19 to the heart of your punitive claims. The  
20 objection is sustained. The deposition of  
21 Mr. Kirkemo cannot be played, and the portions  
22 Mr. Minoul's deposition that refer to the  
23 E-mail cannot be played.  
24 MR. SLATER: It will be edited out,  
25 Your Honor.

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2 THE COURT: Great. Is there anything  
3 further that we can accomplish this evening?  
4 MR. SPECTER: No, sir.  
5 MS. ISMAIL: No, Your Honor.  
6 THE COURT: Thank you, see you at  
7 9:30 tomorrow morning -- actually, let's do  
8 this. Well, what is first? The first one is  
9 Selman, right, that there may be objections  
10 on. So we can do that while other videos are  
11 playing.  
12 MS. ISMAIL: I believe the first  
13 witness will be live.  
14 THE COURT: That's right, but even when  
15 we get into videos, we still have plenty of  
16 time to deal with any objections that may  
17 still exist, right?  
18 MS. ISMAIL: I believe so, Your Honor.  
19 THE COURT: Okay. See you tomorrow at  
20 9:30.  
21 - - -  
22 (Hearing is adjourned at 4:43 p.m.)  
23 - - -  
24  
25

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2  
3 I HEREBY CERTIFY THAT THE PROCEEDINGS  
4 AND EVIDENCE ARE CONTAINED FULLY AND ACCURATELY IN  
5 THE NOTES TAKEN BY ME ON THE TRIAL OF THE ABOVE  
6 CAUSE, AND THAT THIS COPY IS A CORRECT TRANSCRIPT OF  
7 THE SAME.  
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9 JUDITH ANN ROMANO, RPR-CM-CRR  
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